04-21-03 2166

Please type a plus sign (+) inside this box →

PTO/SB/21 (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	10/023,254
Filing Date	17 Dec. 2001
First Named Inventor	Alex. Goen SZYNALSKI
Group Art Unit	2166
Examiner Name	unassigned
Total Number of Pages in This Submission	
Attorney Docket Number	Goen Group, Inc.

ENCLOSURES *(check all that apply)*

- [x] Fee Transmittal Form
- [x] Fee Attached
- [ ] Amendment / Reply
- [ ] After Final
- [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Response to Missing Parts/ Incomplete Application
- [ ] Response to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Assignment Papers *(for an Application)*
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [x] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
- [ ] After Allowance Communication to Group
- [ ] Appeal Communication to Board of Appeals and Interferences
- [ ] Appeal Communication to Group *(Appeal Notice, Brief, Reply Brief)*
- [ ] Proprietary Information
- [ ] Status Letter
- [ ] Other Enclosure(s) *(please identify below):*

Remarks

These papers are being submitted by facsimile with a confirmation copy by Express Mail.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm *or* Individual name	Pharmaceutical Patent Attorneys, LLC Pohl & Assoc.
Signature	
Date	See below date

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on this date: see below date

Typed or printed name	Mark POHL		
Signature		Date	18 April 2003

PTO/SB/17 (10-01)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

FEE TRANSMITTAL for FY 2002

Patent fees are subject to annual revision.

TOTAL AMOUNT OF PAYMENT ($) 130.00

Complete if Known	
Application Number	10/023,254
Filing Date	17 Dec. 201
First Named Inventor	Alexander Goen SZYNALSKI
Examiner Name	unassigned
Group Art Unit	2166
Attorney Docket No.	Goen Semi[illegible]

COPY

METHOD OF PAYMENT

1. ☐ The Commissioner is hereby authorized to charge indicated fees and credit any overpayments to:

Deposit Account Number

Deposit Account Name

☐ Charge Any Additional Fee Required Under 37 CFR 1.16 and 1.17

☐ Applicant claims small entity status. See 37 CFR 1.27

2. ☑ **Payment Enclosed:**

☐ Check ☑ Credit card ☐ Money Order ☐ Other

The PTO did not receive the following listed item(s) Credit Card

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
101	740	201	370	Utility filing fee	0.00
106	330	206	165	Design filing fee	0.00
107	510	207	255	Plant filing fee	
108	740	208	370	Reissue filing fee	
114	160	214	80	Provisional filing fee	

SUBTOTAL (1) ($) 0.00

2. EXTRA CLAIM FEES

	Extra Claims		Fee from below	Fee Paid
Total Claims	0	-20** = 0	X 9.00	= 0.00
Independent Claims	6	- 3** = 3	X 42.00	= 0.00
Multiple Dependent				= 0.00

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
103	18	203	9	Claims in excess of 20
102	84	202	42	Independent claims in excess of 3
104	280	204	140	Multiple dependent claim, if not paid
109	84	209	42	** Reissue independent claims over original patent
110	18	210	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) 0.00

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
105	130	205	65	Surcharge - late filing fee or oath	0.00
127	50	227	25	Surcharge - late provisional filing fee or cover sheet	0.00
139	130	139	130	Non-English specification	0.00
147	2,520	147	2,520	For filing a request for *ex parte* reexamination	0.00
112	920*	112	920*	Requesting publication of SIR prior to Examiner action	0.00
113	1,840*	113	1,840*	Requesting publication of SIR after Examiner action	0.00
115	110	215	55	Extension for reply within first month	0.00
116	400	216	200	Extension for reply within second month	0.00
117	920	217	460	Extension for reply within third month	0.00
118	1,440	218	720	Extension for reply within fourth month	0.00
128	1,960	228	980	Extension for reply within fifth month	0.00
119	320	219	160	Notice of Appeal	0.00
120	320	220	160	Filing a brief in support of an appeal	0.00
121	280	221	140	Request for oral hearing	0.00
138	1,510	138	1,510	Petition to institute a public use proceeding	0.00
140	110	240	55	Petition to revive - unavoidable	0.00
141	1,280	241	640	Petition to revive - unintentional	0.00
142	1,280	242	640	Utility issue fee (or reissue)	0.00
143	460	243	230	Design issue fee	0.00
144	620	244	310	Plant issue fee	0.00
122	130	122	130	Petitions to the Commissioner	130.00
123	50	123	50	Processing fee under 37 CFR 1.17(q)	0.00
126	180	126	180	Submission of Information Disclosure Stmt	0.00
581	40	581	40	Recording each patent assignment per property (times number of properties)	0.00
146	740	246	370	Filing a submission after final rejection (37 CFR § 1.129(a))	0.00
149	740	249	370	For each additional invention to be examined (37 CFR § 1.129(b))	0.00
179	740	279	370	Request for Continued Examination (RCE)	0.00
169	900	169	900	Request for expedited examination of a design application	0.00

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($) 130.00

SUBMITTED BY				Complete (if applicable)	
Name (Print/Type)	Mark POHL, Esq.	Registration No. (Attorney/Agent)	35,325	Telephone	(973) 984-0076
Signature				Date	18 Apr 03

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

PTO/SB/97 (08-00)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Certificate of Transmission under 37 CFR 1.8

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office

on 18 April 2003
Date

Signature

Mark POHL
Typed or printed name of person signing Certificate

Note: Each paper must have its own certificate of transmission, or this certificate must identify each submitted paper.

The submitted papers are enumerated on the enclosed Transmittal Form, PTO Form SB/21.

#6 Pet No Make Special
S. Zimmerman

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor	:	Alexander Goen SZYNALSKI
Serial No.	:	10/023,254
Filing Date	:	17 Dec. 2001
Title	:	*Stop Smoking Methods and Compositions*
Group Art	:	2166
Examiner	:	unassigned

Commissioner of Patents and Trademarks
Box - Petition
Washington, DC 20231
Attention: John LOVE, Esq.,
Director, Art Unit 2160: Facsimile (703) 305-3719
BY FACSIMILE AND
EXPRESS MAIL

PETITION TO MAKE EXAMINATION SPECIAL
UNDER 37 C.F.R. 1.17(h)

Applicant respectfully requests that examination of this Application and any continuation application be made Special pursuant to MANUAL PAT. EXAM. PROC. §708.02 ¶ II (2001).

STATEMENT OF FACTS

THERE IS AN INFRINGING DEVICE OR PRODUCT ON THE MARKET OR METHOD IN USE

1. There is an infringing device or product on the market or method in use. The parent application (now issued as U.S. 6,431,874)[1] is currently in infringement litigation. The same methods accused of infringing the claims of the '874 patent also infringe the pending claims of the immediate '254 application. We therefore first compare the invention to the prior art, to show how the prior art limits the scope of both the '874 claims and the pending '254 application claims. We then make a "rigid comparison" of certain of

[1] True and correct copies of the documents cited here are attached as Exhibits. An Exhibit Table of Contents appears immediately following the signature page of this PETITION.

The Parent Patent

2. The invention relates to a method to stop cigarette smoking. The prior art discloses many stop-smoking products and methods. These include, for example:

(A) education to educate smokers regarding smoking, its physiological dangers and addictive nature, and conscious techniques to stop smoking;

(B) hypnosis, to use the unconscious mind to stop smoking; and

(C) nutritional supplements, addressing the nutritional challenges with regard to stopping smoking.

See SPECIFICATION at page 1, lines 10-16. Using each of these elements separately is known in the art. Id. at 18. The Inventor found, however, that by combining these three elements together, they are synergistically effective in helping people to stop smoking. Id. at 18-24.

3. The Inventor accordingly applied for a patent on 27 Oct 1999. That application, Serial No. 09/427,447, is the parent of the immediate application. The claims as originally filed recited the three-part combination of (A) education, (B) hypnosis, and (C) lobelia. Lobelia is an herbal antidepressant. Id. at 13-15. Antidepressants are known as stop-smoking aids. *E.g.*, AMENDMENT (19 Sept 01) (copy enclosed).

4. The prior art of record failed to show any suggestion to combine elements (A) + (B) + lobelia. More, the art of record failed to suggest combining elements (A) + (B) + any other stop-smoking substance.

5. Then, the Applicant and Examiner held an Interview. *See* INTERVIEW SUMMARY (19 Sept 2001). In response, the "Examiner agreed to consider claims addressed to anti-depressants instead of lobelia, but requested efficacy in this usage." Id. In response, Applicant amended claim element (C) from "lobelia" to "anti-smoking drug." Applicant explained, "Element C is broadened to encompass equivalents of lobelia literally." *See* AMENDMENT (19 Sept 01) at page 5, lines 2-3.

6. The Examiner initially believed that because "the term 'anti-smoking drug' can encompass prescription pharmaceuticals, it is far broader in scope than the recitation of Lobelia found in the disclosure." *See* OFFICE ACTION at page 2 (4 Dec. 2001).

7. Applicant in response pointed out that the disclosure as filed in fact enumerates several antidepressants other than lobelia, and the three-part combination (A)+(B)+anti-smoking drug was nowhere suggested in the art of record. *See* INTERVIEW SUMMARY (14 Dec 01).

8. A NOTICE OF ALLOWABILITY was accordingly issued. That NOTICE, however, erroneously included an Examiner's Amendment changing the claim term from "anti-smoking drug" to "lobelia." *See* NOTICE OF ALLOWABILITY (14 Dec. 01). The error was corrected with a CORRECTED NOTICE OF ALLOWABILITY. *See* CORRECTED NOTICE OF ALLOWABILITY (4 Feb. 02). The CORRECTED NOTICE OF ALLOWABILITY removed the erroneous Examiner's Amendment, and leaves the claim term "anti-smoking drug" intact.

9. The parent application accordingly matured into U.S. Letters Patent No. 6,431,874 (13 Aug. 2002). Claim 1 of the '874 patent reads:

"A method for helping a tobacco smoker to stop smoking, ... comprising the steps of

(A) providing to the tobacco smoker a non-conditioning, educational program ...,

(B) providing to said tobacco smoker at least one hypnosis program ..., and

(C) providing to said tobacco smoker an anti-smoking drug."

See U.S. '874 at col. 12, lines 15-32.

The Pending Federal Court Litigation

10. On receiving the '874 patent, the Applicant made a rigid comparison of the issued parent claims to the method practiced by Gorayeb Seminars Institute, Inc. of Rockaway, New Jersey.

11. The Gorayeb Seminars method appears to be a precise, slavish copy of Applicant's patented method. Newspaper advertising for both the Applicant ("Goen Seminars") and the accused infringer ("Gorayeb Seminars") is attached. *Compare* Goen Seminars Inc., *Stop Smoking Seminar with Hypnosis 110% Seminar Guarantee** (March 2001) *with* Gorayeb Seminars Inc., *Stop Smoking with Hypnosis 110% Seminar Guarantee** (Nov. 2002).

12. Thus, on receiving the '874 patent, the Applicant sent Gorayeb Seminars a copy of it and offered a license to it. Gorayeb Seminars refused to even discuss a license. Despite having notice of the '874 patent, Gorayeb Seminars continued to copy the patented method.

13. Applicant thus sued Gorayeb Seminars for infringing the '874 patent.

14. In response, Defendant Gorayeb Seminars has denied infringement, saying, *inter alia*, that the '874 patent is unenforceable because it was "never granted" and bears "substantive printing errors" by the Patent Office. DEFENDANT'S ANSWER at ¶ 24 (10 April 03) ("plaintiff's attempt to enforce the false claims of the printed patent, which plaintiff knows were never granted"; the '874 patent "contain[s] false claims due to substantive printing errors.").

15. The Defendant's allegation that the '874 patent "was never granted" and bears "substantive printing errors" makes it important for the pending '254 application to be examined immediately, because the pending application contains claims which are unquestionably infringed - regardless of whether the '874 patent "was never granted," or what "substantive printing errors" are alleged.

A RIGID COMPARISON OF THE ALLEGED INFRINGING DEVICE, PRODUCT OR METHOD WITH THE APPLICATION CLAIMS HAS BEEN MADE AND SOME OF THE CLAIMS ARE UNQUESTIONABLY INFRINGED.

16. Applicant has made a rigid comparison of the alleged infringing method with the pending application claims. Some of the claims are unquestionably infringed.

17. A complete copy of the pending application claims are attached. *See* PRELIMINARY AMENDMENT at 8-11 (7 Nov. 02). Application claim 1 recites:

> 1. A method for helping a subject to stop smoking, said method comprising:
> (A) providing a non-conditioning educational program to educate the conscious mind to discourage smoking behavior;
> (B) providing a hypnosis program to train the subconscious mind to discourage smoking behavior; and
> (C) providing a substance selected from the group consisting of:
> a stop-smoking substance in an amount effective to aid in the reduction or cessation of a craving to smoke tobacco;

> a weight control substance in an amount effective to control body weight; and
> a dietary supplement in an amount effective to supplement the diet.

Id. at page 8, lines 4-13. In contrast, claim 2 recites "The method of claim 1, wherein said substance comprises a stop-smoking substance in an amount effective to aid in the reduction or cessation of a craving to smoke tobacco. Id. at lines 14-16.

18. The Gorayeb Seminar provides to the tobacco smoker (the seminar attendee) an educational program. The educational program includes a printed sixteen-page brochure. *See* Gorayeb Seminars Inc., STOP SMOKING – PRODUCING A DIFFERENCE (2002). The brochure is distributed to Gorayeb Seminar attendees. The brochure provides education on the *disadvantages of smoking.* For example, the brochure discusses "The Dollar Cost of Smoking" and "The Health Cost of Smoking," and "How and Why Cigarettes Are Very Addictive." Id. at 2. The financial cost, health cost and addictiveness of smoking are disadvantages of smoking. Similarly, the brochure provides education on *conscious techniques to stop smoking.* The brochure explains the conscious technique of "Using Food as an Aid To Stop Smoking" and "Handling Urges." Id. at 6-7. These conscious techniques are described in the brochure itself as "Aid To Stop Smoking." Id. at 6. Because the brochure provides education on "a non-conditioning educational program to educate the conscious mind to discourage smoking behavior," the Gorayeb Seminar has claim element (A).

19. The Gorayeb Seminar has hypnosis. The Gorayeb Seminar newspaper advertisement says:

> You will experience two hypnotic sessions this evening to eliminate your desire and craving for cigarettes. With our method of clinical hypnosis you enter a deep, relaxed state of hypnosis where you are awake, aware and IN CONTROL. By tapping the power of your subconscious mind, the hypnosis is designed to eliminate your craving for cigarettes in everyday life situations ... the hypnosis is designed so you will leave this seminar as a NON-SMOKER.

See Gorayeb Seminars Inc., *Stop Smoking with Hypnosis 110% Seminar Guarantee** (7 Nov. 2002). To confirmed whether the Gorayeb Seminar does in fact provide hypnosis as

advertised, I attended a Gorayeb Seminar session. The Gorayeb Seminar does provide hypnosis as advertised. The seminar entailed, *inter alia*, instructing the tobacco user to imagine picking from a full ash tray a stranger's used cigarette butt, placing it in the tobacco user's mouth, and chewing it slowly. The hypnosis session also entailed instructing the tobacco user to imagine the brand of cigarette the tobacco user smokes, and, as it is mentally pictured, instructing the tobacco user to say to themselves, "seven minutes of life gone – what a waste," and instructing the tobacco user to imagine painting a blood red NO over the cigarette, and saying to themselves, "NO desire." This in-person hypnosis protocol is recapitulated in the "Mental Training Exercise" given in the Gorayeb Seminar brochure (copy attached).

20. Additionally, the Gorayeb Seminar brochure advertises a variety of hypnosis programs on cassette tape. Id. at pages 9, 11. These include the "Stop Smoking Hypnosis Reinforcement Tape," the Stop Smoking Subliminal Tape" and the "Personal Hypnosis Library." Id. These tapes are sold at the Gorayeb Seminar. Photocopies of a variety of hypnosis cassette tapes offered for purchase at the Gorayeb Seminar are attached.

21. Thus, the Gorayeb Seminar provides, as specified in patent claim element (B), "a hypnosis program to train the subconscious mind to discourage smoking behavior."

22. Pending application claims 1 and 2 recite, "(C) providing ... a stop-smoking substance in an amount effective to aid in the reduction or cessation of a craving to smoke tobacco." The Gorayeb Seminar includes this. The Gorayeb Seminar brochure advertises atmleast one stop-smoking substance, Nicazan™. This product is sold at the Gorayeb Seminar.

23. The Nicazan™ label (copy enclosed) says, "STOP SMOKING SUPPLEMENT," "STRESS RELIEF" and "CRAVING RELIEF." The Nicazan™ label itself thus says that Nicazan™ is a stop-smoking substance as required by claim element (C). The ingredients listed on the Nicazan™ label confirms this. Ingredients include 5-HTP, DL-phenylalanine, L-Glutamine, Folate, and something called "smokestop blend." The Gorayeb Seminars brochure (Gorayeb Seminars Inc., *Stop Smoking with Hypnosis 110% Seminar Guarantee**

(7 Nov. 2002)) explains that each of these is a stop-smoking substance within the meaning of claim 1 and 2. The brochure at page 14 explains that 5-HTP:

> is an important amino acid ... that the body uses to produce the neurotransmitter Serotonin. Serotonin produces feelings of strength, well being and influences our mood. Proper serotonin levels also relieves depressed feelings and may help relieve nicotine withdrawal symptoms. Most prescription drugs designed to control depression work by artificially increasing Serotonin levels. 5-HTP works naturally instead, allowing the body to produce Serotonin just as it needs to feel better. 5-HTP is a precursor to Serotonin which is a precursor to Melatonin. Melatonin helps promote sleep and relaxation.

Thus, 5-HTP "produce[s] a calming effect within the body, thereby relieving the stress associated with nicotine withdrawal symptoms"; 5-HTP is therefore a stop-smoking substance within the meaning of pending claims 1 and 2.

24. Similarly, the Gorayeb Seminars brochure at page 14 explains that DL-phenylalanine is:

> An amino acid that is utilized by the body for numerous functions including synthesis into Dopamine. ... Drug addiction research has found this amino acid to be an effective treatment for relieving the physical cravings caused by addictive drugs like nicotine. ... This helps relieve withdrawal symptoms naturally, allowing gradual recovery. DLPA has been shown to help maintain natural body chemicals known as encephalins, which are the brains own analgesic (pain killer). This helps to relieve withdrawal.

Thus, DL-phenylalanine "produce[s] a calming effect within the body, thereby relieving the stress associated with nicotine withdrawal symptoms"; DL-phenylalanine is therefore a stop-smoking substance within the meaning of pending claims 1 and 2.

25. Similarly, the Gorayeb Seminars brochure at pages 14-15 explains that L-Glutamine is "involved in the synthesis of numerous neurotransmitters including Gaba which has a wonderful calming effect," and that Folate, "when combined with vitamins B-6 and B-12 [both present in Nicazan™], published research has shown it to relieve feelings of depression and anxiety." Thus, both L-Glutamine and Folate "produce a calming effect within the body, thereby relieving the stress associated with nicotine withdrawal

symptoms"; they are each therefore a stop-smoking substance within the meaning of the patent.

26. Recall that the claims 1 and 2 require the stop-smoking substance be provided "in an amount effective to aid in the reduction or cessation of a craving to smoke tobacco." Here, the Nicazan™ label also directs, "Take 1 tablet, 3 times/day ... if you smoked 1 pack/day. If you smoked more, take 1 tablet, 4-6 times/day." These dosage levels appear to be "in an amount effective to aid in the reduction or cessation of a craving to smoke tobacco," as described by the patent claim.

27. Thus, the Gorayeb Seminar is:

> A method for helping a subject to stop smoking, said method comprising:
> (A) providing a non-conditioning *educational program* to educate the conscious mind to discourage smoking behavior;
> (B) providing a *hypnosis program* to train the subconscious mind to discourage smoking behavior; and
> (C) ... a *stop-smoking substance* in an amount effective to aid in the reduction or cessation of a craving to smoke tobacco;

Practicing the Gorayeb Seminar therefore literally infringes at least pending claims 1 and 2.

THE INVENTOR OF RECORD HAS A GOOD KNOWLEDGE OF THE PRIOR ART.

28. The Inventor of record has a good knowledge of the prior art. *See* SPECIFICATION at page 1, line 25 to page 2, line 14. Copies of each of the prior art references deemed most closely related to the pending claims are already of record in this case.

POINT TO BE REVIEWED

Whether examination of the application may be accelerated under M.P.E.P. § 708.02(II)?

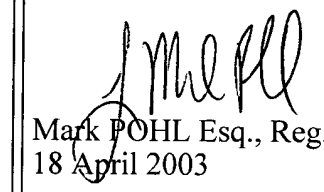
ACTION REQUESTED

Applicant respectfully requests that examination of the application (and any continuation or divisional application) be made special.

ENCLOSURES

A FEE TRANSMITTAL FORM and the required petition fee are enclosed. The references most closely related have already been made of record.

Respectfully submitted,



Mark POHL Esq., Reg. No. 35,325
18 April 2003

Pharmaceutical Patent Attorneys LLC,
Pohl & Assoc.
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Attn : M. POHL (P 4014)
Morristown, NJ 07960-6397

Direct ☎ (973) 984-0076
Mark.Pohl@LicensingLaw.Net

Mbc:mp
Enclosures

T:\SD\Goen\Goen Seminars\10/023,254 Petition-Special II

TAB	EXHIBITS
1	Interview Summary (19 Sept 01)
2	Amendment (19 Sept 01)
3	Office Action (4 Dec 01)
4	Interview Summary (14 Dec. 01)
5	Notice of Allowability (14 Dec. 01)
6	Corrected Notice of Allowability (4 Feb. 02)
7	U.S. Letters Patent No. 6,431,874 (13 Aug. 02)
8	Goen Seminars Inc., *Stop Smoking Seminar with Hypnosis 110% Seminar Guarantee** (March 2001); Gorayeb Seminars Inc., *Stop Smoking with Hypnosis 110% Seminar Guarantee** (7 Nov. 2002)
9	Goen Seminars Inc. v. Gorayeb Seminars Inc. (D.N.J. 2003); DEFENDANT'S ANSWER at ¶ 24 (10 April 03)
10	PRELIMINARY AMENDMENT (7 Nov. 02)
11	Gorayeb Seminars, Inc., Nicazan™ product label; hypnosis cassette tapes; Isotrim-CX™ product label; Gorayeb Seminars Inc., STOP SMOKING – PRODUCING A DIFFERENCE (2002)
12	

Interview Summary

Application No.	Applicant(s)	
09/427,447	SZYNALSKI, ALEXANDER GOEN	
Examiner	**Art Unit**	
Sam Rimell	2166	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Sam Rimell*. (3)_____.

(2) *Mark Pohl*. (4)_____.

Date of Interview: *19 September 2001* .

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☒ No.
If Yes, brief description: _____ .

Claim(s) discussed: *1 and 11* .

Identification of prior art discussed: *Cooper et al.* .

Agreement with respect to the claims f)☐ was reached. g)☐ was not reached. h)☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *Examiner suggested modifying claims 1 and 11 to define non-invasive educational techniques, unlike those of Cooper et al. which are invasive to the body. Examiner agreed to consider claims addressed to the use of anti-depressants instead of lobelia, but requested information on efficacy in this usage* .

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

i)☐ It is not necessary for applicant to provide a separate record of the substance of the interview(if box is checked).

Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

Please type a plus sign (+) inside this box →

PTO/SB/21 (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	09/427,447
Filing Date	27 Oct 1999
First Named Inventor	Alexander Goen SZYNALSKI
Group Art Unit	2166
Examiner Name	Samuel RIMELL, Esq.
Total Number of Pages in This Submission	
Attorney Docket Number	Nutrimerica

ENCLOSURES *(check all that apply)*

- ☑ Fee Transmittal Form
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- ☐ CD, Number of CD(s) one
- ☐ After Allowance Communication to Group
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to Group *(Appeal Notice, Brief, Reply Brief)*
- ☐ Proprietary Information
- ☐ Status Letter
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Remarks

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Date	See below date

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Typed or printed name	Mark POHL, Reg. No. 35,325
Signature	Date 19 Sept 01

IN THE UNITED STATES PATENT OFFICE

Inventor	: Alexander Goen SZYNALSKI
Serial No.	: 09/427,447
Filing Date	: 27 Oct 1999
Title	: Stop Smoking Methods
Group Art Unit	: 2166
Examiner	: Samuel RIMELL, Esq.

Assistant Commissioner of Patents
Washington, DC 20231

AMENDMENT

Please amend pending claims 1 and 11 to read:

1. A method for helping a tobacco smoker to stop smoking, said method comprising the steps of:

(A) providing to a tobacco smoker ~~an~~ non-conditioning, educational program to educate said tobacco smoker's conscious mind, said educational program including education both on the disadvantages of smoking and on conscious techniques to stop smoking,

(B) providing to said tobacco smoker at least one hypnosis program to train said tobacco smoker's subconscious mind to discourage said tobacco smoker from performing smoking behavior, and

(C) providing to said tobacco smoker ~~lobelia~~ an anti-smoking drug in an amount effective to aid in the reduction or cessation of said tobacco smoker's craving to smoke tobacco,

such that said tobacco smoker can be helped to stop smoking.

11. A product to aid a tobacco smoker in ceasing to smoke tobacco, said product comprising:

(A) means for educating said tobacco smoker's conscious mind, said educational program including non-conditioning education both on the disadvantages of smoking and on conscious techniques to stop smoking,

(B) means for hypnosis to train said tobacco smoker's subconscious mind to discourage said tobacco smoker from performing smoking behavior, and

(C) ~~lobelia~~ an anti-smoking drug in an amount effective to aid in the reduction or cessation of said tobacco smoker's craving to smoke tobacco.

A clean copy of claims 1 and 11 thus read:

1. A method for helping a tobacco smoker to stop smoking, said method comprising the steps of:

(A) providing to a tobacco smoker a non-conditioning, educational program to educate said tobacco smoker's conscious mind, said educational program including education both on the disadvantages of smoking and on conscious techniques to stop smoking,

(B) providing to said tobacco smoker at least one hypnosis program to train said tobacco smoker's subconscious mind to discourage said tobacco smoker from performing smoking behavior, and

(C) providing to said tobacco smoker an anti-smoking drug in an amount effective to aid in the reduction or cessation of said tobacco smoker's craving to smoke tobacco,

such that said tobacco smoker can be helped to stop smoking.

11. A product to aid a tobacco smoker in ceasing to smoke tobacco, said product comprising:

(A) means for educating said tobacco smoker's conscious mind, said educational program including non-conditioning education both on the disadvantages of smoking and on conscious techniques to stop smoking,

(B) means for hypnosis to train said tobacco smoker's subconscious mind to discourage said tobacco smoker from performing smoking behavior, and

(C) an anti-smoking drug in an amount effective to aid in the reduction or cessation of said tobacco smoker's craving to smoke tobacco.

Please withdraw the previous cancellation of claims 7, 8, 17 and 18. Please add new claims 21-24:

21. The method of claim 1, wherein said anti-smoking drug is an antidepressant.

22. The method of claim 21, wherein said antidepressant is lobelia.

23. The product of claim 11, wherein said anti-smoking drug is an antidepressant.

24. The product of claim 23, wherein said anti-depressant is lobelia.

REMARKS

Claims 1, 6, 11 and 16 are pending in the application. Claims 1 and 11 stand rejected in light of Cooper *et al.*

Claims 1 and 11

Amendments are made to elements (A) and (C).

Element (A) - "an educational program"

Cooper cannot anticipate claims 1 and 11 because Cooper fails to teach an essential claim element.

The claims require three elements: "(A) education...; (B) hypnosis, to use *the unconscious mind* to stop smoking; and (C) nutritional supplements addressing the nutritional challenges with regard to stopping smoking." Specification at 1. These three elements act on "the *conscious* mind, the *unconscious* mind, and the *body*." Id.

The unconscious mind is programmed using repetition of stimuli, to take the subject toward pleasure and away from pain. Id. at 7. The Specification discusses numerous methods for programming the unconscious, id. at 7-10. Methods of programming the unconscious mind are referred to as "hypnosis." In the preferred embodiment, such hypnosis involves, for example, negative conditioning. Id. at 8. ("hypnosis focuses on interrupting 'conditioned responses' generally, and specifically, on interrupting the response to smoke").

Conditioning is "A process of behavior modification by which a subject comes to associate a desired behavior with a previously **unrelated** stimulus." American Heritage Dictionary (2000) (available at *www.dictionary.com*). Conditioning was discovered by I.P. PAVLOV, who trained dogs to perform an unconscious response (salivation) in response to an unrelated stimulus (a bell). On-Line Medical Dictionary (12 Dec 1998).

Cooper teaches a "negative conditioning" apparatus. Conditioning is a method of programming *unconscious* response. It is not an educational program for the conscious mind. The claims have been amended to clarify that "conditioning" is a type of hypnosis, not a type of education.

Element (C) - "lobelia"

Element C is broadened to encompass equivalents of lobelia literally.

The Specification teaches that lobelia is an antidepressant acetylcholine receptor binder. Specification at 13-15. The Specification teaches other examples of antidepressants, id. at 18 (gotu kola extract; kava kava root).

It is known in the art that antidepressants can be used as stop-smoking drugs. For example, buproprion hydrochloride is sold as both an antidepressant (commercially available under the trademark WELLBUTRIN® from Glaxo-Wellcome Inc., Chapel Hill, North Carolina) and a stop-smoking drug (commercially available under the trademark ZYBAN® from Glaxo-Wellcome Inc., Chapel Hill, North Carolina). Physicians' Desk Reference at 1277 *et seq.* (1999). Antidepressants "produce[] a calming effect within the body, thereby relieving the stress associated with nicotine withdrawal symptoms." Specification at 18, lines 8-9. This probably explains why individuals quitting smoking feel better when taking an anti-smoking drug. Id. at 15, lines 12-14.

Accordingly, element (C) is broadened to encompass stop-smoking drugs generally, and dependent claims 21-24 are added to recite lobelia specifically.

Claims 7, 8, 17 and 18

These claims were previously rejected as allegedly non-enabled under Section 112, first paragraph. The claims were then withdrawn based on the understanding that the remaining claims would proceed to prompt allowance. The 24 Oct 2001 Office Action moots the reason to have withdrawn these claims.

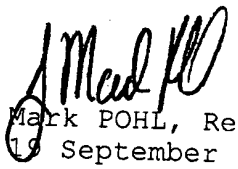
These claims comply with 35 USC 112. Claims 7 and 17 recite "at least one weight-control product." Claims 8 and 18 require the weight control product to include a stimulant.

Weight control products ("anorexants"), the use of CNS stimulants as such, and the therapeutically effective amounts, are known nearly universally in the United States. *See e.g.*, The Merck Manual at 2492-93 (1987) ("CNS stimulants are used to … suppress the appetite. *** The failure of most obese patients to lose weight satisfactorily by attempting to decrease food intake alone has led to widespread use of anorexants. Amphetamine and related compounds … are most effective for the first 3 to 6 wk."). CNS stimulants which are used as anorexants in include amphetaminil, benzphetamide, chlorphentermine, clortermine, dextroamphetamine sulfate, diethylpropion, n-ethylamphetamine, mazindol, methamphetamine, and others. *See* The Merck Index (1996). The Specification need not disclose subject matter already common knowledge in the art.

SUMMARY

All pending claims are believed patentable over the art. Prompt allowance is respectfully requested.

Respectfully Submitted,



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19 September 2001

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100 mg have been used in severely resistant patients. For maintenance, dosage is reduced to the smallest effective amount. Haloperidol is readily absorbed orally. Peak plasma concentration occurs 2 to 6 h after ingestion and may plateau for as long as 72 h; plasma levels may be detectable for weeks. In acute cases, haloperidol 2 to 5 mg IM may be given.

Haloperidol potentiates the effect of CNS depressants and anticoagulants. It diminishes the effect of L-dopa. It can diminish dyskinesia but aggravates parkinsonism in patients on L-dopa therapy. Since prolonged neuroleptic therapy is associated with development of tardive dyskinesias, haloperidol is not recommended for the treatment of tardive dyskinesias or L-dopa dyskinesias because it can mask the worsening of neuroleptic-related tardive dyskinesias.

THIOXANTHENES

Of the 4 thioxanthenes marketed in various countries, only **chlorprothixene** and **thiothixene** are available in the USA for clinical use. The thioxanthenes resemble the phenothiazines in chemical structure, absorption, metabolism, excretion, and clinical effects. Chlorprothixene and thiothixene have been used in the treatment of schizophrenia and depression. The average oral daily adult dosage is 75 to 200 mg for chlorprothixene and 10 to 30 mg for thiothixene; however, individual patient requirements vary.

Like other neuroleptics, the thioxanthenes interfere with conditioned reflex activity without affecting unconditioned reflex activity. They increase limbic system activity and inhibit proprioceptive arousal reactions. Psychoactive thioxanthenes share some of the properties of tricyclic antidepressants. Thiothixene is comparable to chlorpromazine in therapeutic impact and is particularly effective against affective symptoms. It is especially useful for patients who are socially withdrawn, and is also effective in the management of psychotic depression, tension-agitation, and anxiety.

Fever, fatigue, and drowsiness are the most frequent adverse effects. The sensitivity to sunlight seen with phenothiazines is usually not observed. The relative frequency of adverse effects with thiothixene is lower than with the corresponding phenothiazine analogs. The lower incidence of extrapyramidal effects in long-term maintenance therapy is especially advantageous. Thiothixene has fewer adverse effects on the myocardium than does thioridazine.

OTHER ANTIPSYCHOTIC DRUGS

Loxapine, a tricyclic dibenzoxazepine derivative, is chemically distinct from thioxanthenes, butyrophenones, and phenothiazines. Its pharmacologic and toxicologic properties are similar to those of the piperazine group of phenothiazines. Therapeutic efficacy is comparable with that of other neuroleptics in schizophrenia. Side effects include involuntary movements, hypotension, and somnolence. Oral doses range from 60 to 100 mg/day, although some patients may require up to 250 mg/day.

Molindone, a dihydroindolone derivative, is structurally different from the phenothiazines, butyrophenones, and thioxanthenes, but is also pharmacologically similar to the phenothiazines. The daily oral dose range is 20 to 200 mg.

GENERAL CENTRAL NERVOUS SYSTEM STIMULANTS AND ANOREXIANTS

CNS stimulants are used to increase alertness, inhibit fatigue, suppress the appetite, manage certain children with minimal brain dysfunction or hyperkinesis, and treat narcolepsy. Many of these drugs are related to amphetamine and share the phenethylamine structure. Their activity as psychostimulants is primarily due to an ability to act

indirectly by displacing endogenous catecholamines from storage sites in neural tissues, but may also be partly related to direct catecholamine-like adrenergic receptor activation in the CNS. Their use in clinical medicine continues to decline because of criticism of any use to induce brief mood elevation or to suppress fatigue and a fear that nonchalant prescribing may have contributed to abuse (see also Ch. 138).

The failure of most obese patients to lose weight satisfactorily by attempting to decrease food intake alone has led to widespread use of anorexiants. Though these drugs may be of value in beginning a weight reduction program, their long-term utility has been questioned. Amphetamine and related compounds such as diethylpropion, phentermine, and phendimetrazine are most effective for the first 3 to 6 wk. The suggestion that they might be useful intermittently over a long period to aid in weight control has been made. The dosage usually is divided and given before meals, but some agents have a long duration of action and may be given less frequently. Most anorexiants may disturb sleep if given late in the day. The use of agents less subject to abuse than amphetamine or phenmetrazine is recommended whenever feasible.

Amphetamine is the prototype CNS stimulant. There are a variety of amphetamine salts and mixtures in various formulations. Amphetamine produces mood elevation with increased wakefulness, alertness, concentration, and physical performance. Systolic and diastolic blood pressures are raised, the respiratory center is stimulated, and appetite is suppressed through a central effect. It is rapidly absorbed from the GI tract, reaches high concentrations in the CNS, and is largely metabolized. Its prolonged duration of sympathomimetic action relates to its resistance to metabolic degradation by enzymes that metabolize catecholamines. Amphetamine and related compounds, when taken repeatedly, induce tolerance to some degree, but this is partially dependent on dosage.

Insomnia, dizziness, excessive sweating, tremors, and euphoria may occur, and feelings of depression and fatigue often accompany withdrawal. Anxiety and panic states are seen, particularly at the high dosage levels associated with amphetamine abuse. Lethal overdose is uncommon because of the large difference between an effective and fatal dose and because tolerance has often occurred. For a detailed discussion of amphetamine abuse and its management, see Ch. 138.

Methylphenidate is a CNS stimulant with effects similar to that of amphetamine. It is used to treat hyperkinesis in children (see LEARNING DISORDERS in Ch. 188) and for narcolepsy (see Ch. 122).

Fenfluramine, a newer anorexiant, appears to have minimal abuse potential. Although a phenethylamine, it has sedation as its principal side effect and may be given late in the day without disturbing sleep. It should be *avoided* in patients with a history of mental depression and migraine. Some feel that a low night-time dose of fenfluramine may be combined with a daytime dose of phentermine or diethylpropion for effective and minimally symptom-inducing anorexia.

ANTIEMETICS

Drugs that prevent or relieve nausea and vomiting. Nausea and vomiting may be symptoms of disease processes, eg, metabolic or microbial toxins, or responses to stimuli such as drugs, radiation, or motion. The underlying cause should be sought and corrected if possible, as the etiology suggests which antiemetic is optimal for symptomatic treatment. Nausea and vomiting induced by noncytotoxic drugs such as digitalis, estrogens, and iron preparations should be treated by reducing the dose, changing the route of administration, or switching to another drug.

Stimulation of the vomiting center in the medulla can arise in the chemoreceptor trigger zone (**CTZ**), cerebral cortex, or vestibular apparatus, or can be relayed directly from peripheral areas (eg, gastric mucosa). Though the mechanism of action of the

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CNS STIMULANT *(continued)*

Fenethylline, *4014*
Fenozolone, *4028*
Flurothyl, *4236*
Hexacyclonate Sodium, *4717*
Homocamfin, *4768*
Mazindol, *5801*
Mefexamide, *5844*
Methamphetamine, *6015*
Methylphenidate, *6186*
Modafinil, *6311*
Nikethamide, *6635*
Pemoline, *7206*
Pentylenetetrazole, *7283*
Phendimetrazine, *7365*
Phenmetrazine, *7385*
Phentermine, *7415*
Picrotoxin, *7570*
Pipradrol, *7638*
Prolintane, *7964*
Pyrovalerone, *8194*

COGNITION ACTIVATOR *see Nootropic*

CONTRACEPTIVE (INJECTABLE)

Medroxyprogesterone, *5838*
Norethindrone, *6790*

CONTRACEPTIVE (ORAL)

Desogestrel, *2971*
Ethinyl Estradiol, *3780*
Ethynodiol, *3905*
Gestodene, *4421*
Lynestrenol, *5659*
Mestranol, *5976*
Norethindrone, *6790*
Norethynodrel, *6791*
Norgestimate, *6796*
Norgestrel, *6797*

CONTROL OF INTRAOCULAR PRESSURE *see also Antiglaucoma*

Apraclonidine, *791*

CONVERTING ENZYME INHIBITOR *see ACE-Inhibitor*

CORONARY VASODILATOR *see Vasodilator (Coronary)*

CYTOPROTECTANT (GASTRIC) *see also Antiulcerative*

Aceglutamide Aluminum Complex *see 25*
Acetoxolone, *76*
Benexate Hydrochloride, *4065*
Carbenoxolone, *1839*
Cetraxate, *2067*
Guaiazulene, *4581*
Irsogladine, *5113*
Plaunotol, *7692*
Polaprezinc, *7712*
Rebamipide, *8296*
Sofalcone, *8850*
Spizofurone, *8918*
Sucralfate, *9049*
Teprenone, *9296*
Troxipide, *9921*
Zolimidine, *10320*

DEBRIDING AGENT

Collagenase, *2544*
Deoxyribonuclease I, *2953*
Papain, *7148*

DECONGESTANT

Amidephrine, *418*
Cafaminol, *1671*
Cyclopentamine, *2808*
Ephedrine, *3645*
Epinephrine, *3656*
Fenoxazoline, *4025*
Indanazoline, *4967*
Metizoline, *6223*
Naphazoline, *6455*
Nordefrin Hydrochloride, *6785*
Octodrine, *6854*
Oxymetazoline, *7100*
Phenylephrine Hydrochloride, *7440*
Phenylpropanolamine Hydrochloride, *7461*
Phenylpropylmethylamine, *7462*
Propylhexedrine, *8045*
Pseudoephedrine *see 3641*
Tetrahydrozoline, *9358*
Tramazoline, *9702*
Tuaminoheptane, *9934*
Tymazoline, *9965*
Xylometazoline, *10219*

DEPIGMENTOR

Hydroquinine, *4852*
Hydroquinone, *4853*
Monobenzone, *6331*

DERMATITIS HERPETIFORMIS SUPPRESSANT

Dapsone, *2885*
Sulfapyridine, *9108*

DIAGNOSTIC AID

Alsactide, *322*
Americium, *410*
p-Aminohippuric Acid, *462*
Anazolene Sodium, *669*
Arbutamine, *811*
Arginine, *817*
Bentiromide, *1081*
Betazole, *1230*
Ceruletide, *2048*
Colfosceril Palmitate, *2540*
Congo Red, *2562*
Dexamethasone, *2986*
Edrophonium Chloride, *3562*
Evan's Blue, *3952*
Fluorescein, *4194*
Galactose, *4353*
Glycerol, *4493*
Histamine, *4756*
Indocyanine Green, *4992*
Inulin, *5024*
Iodinated Serum Albumin *see 8613*
Isosulphan Blue *see 9161*
Mannitol, *5788*
Merisoprol Hg 197, *5959*
Methacholine Chloride, *6003*
Metyrapone, *6246*
Oleic Acid, *6965*
Penicilloyl Polylysine, *7233*
3-Pentadecylcatechol, *7244*
Pentagastrin, *7250*
Phenolsulfonphthalein, *7397*
Phenoltetrachlorophthalein, *7398*
Phentolamine, *7417*
Piperoxan, *7631*
Porfimer Sodium, *7755*
Rose Bengal, *8421*
Saralasin, *8518*
Sodium Benzoate, *8725*
Sodium Chromate(VI) Radioactive, *see 8745*
Sodium Iodide, Radioac...
Sulfobromophthalein Sodium
Teriparatide Acetate, *9307*
Tolonium Chloride, *9659*
TSH, *9931*
Tuberculin, *9937*
Tubocurarine Chloride, *9...*
Vitamin B_{12}, Radioactive
Xylose, *10220*

DIAGNOSTIC AID (CONTRAST AGENT)

Gadodiamide, *4345*
Gadopentetic Acid, *4347*
Gadoteridol, *4348*
Perflubron, *7299*

DIAGNOSTIC AID (RADIOACTIVE IMAGING AGENT)

Butedronic Acid Complex with ^{99m}Tc *see 1546*
Disofenin Complex with ^{99m}Tc *see 3422*
Exametazime Complex with ^{99m}Tc *see 3957*
Fludeoxyglucose F^{18}
Iobenguane, *5027*
Iofetamine ^{123}I, *5066*
Lidofenin Complex with *5506*
Medronic Acid Complex with ^{99m}Tc *see 5837*
Oxidronic Acid Complex with ^{99m}Tc *see 7074*
Pamidronic Acid Complex with ^{99m}Tc *see 7135*
Pentetreotide Chelate with *7267*
Satumomab Pendetide *8530*
Sodium Pertechnetate
Sodium Phosphate, Radio... *8807*
Stannous Pyrophosphate with ^{99m}Tc *see 8945*
Succimer Complex with *9034*
Technetium, *9256*
Technetium ^{99m}Tc-Bicis...
Technetium ^{99m}Tc Mer...
Technetium ^{99m}Tc Sest...
Technetium ^{99m}Tc Teb... *9260*
Tetrofosmin Complex with *see 9383*
^{133}Xenon *see 10206*

DIAGNOSTIC AID (RADIOPAQUE MEDIUM)

Acetrizoate Sodium, *79...*
Barium Sulfate, *1023*
Bunamiodyl Sodium
Diatrizoate Sodium, *304...*
Ethiodized Oil, *3781*
Iobenzamic Acid, *5028*
Iocarmic Acid, *5029*
Iocetamic Acid, *5030*
Iodipamide, *5043*
Iodixanol, *5044*

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53

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DOSAGE AND ADMINISTRATION

CAUTION— RAPID OR BOLUS INTRAVENOUS AND INTRAMUSCULAR OR SUBCUTANEOUS INJECTION MUST BE AVOIDED. Therapy should be initiated as early as possible following onset of signs and symptoms. For diagnosis—see INDICATIONS.

Dosage: ***Herpes Simplex Infections: Mucosal and Cutaneous Herpes Simplex (HSV-1 and HSV-2) Infections in Immunocompromised Patients:*** 5 mg/kg infused at a constant rate over 1 hour, every 8 hours (15 mg/kg/day) for 7 days in adult patients with normal renal function. In pediatric patients under 12 years of age, more accurate dosing can be attained by infusing 250 mg/m^2 at a constant rate over 1 hour, every 8 hours (750 mg/m^2/day) for 7 days.

Severe Initial Clinical Episodes of Herpes Genitalis: The same dose given above—administered for 5 days.

Herpes Simplex Encephalitis: 10 mg/kg infused at a constant rate over at least 1 hour, every 8 hours for 10 days. In pediatric patients between 6 months and 12 years of age, more accurate dosing is achieved by infusing 500 mg/m^2, at a constant rate over at least 1 hour, every 8 hours for 10 days.

Varicella Zoster Infections: Zoster in Immunocompromised Patients: 10 mg/kg infused at a constant rate over 1 hour, every 8 hours for 7 days in adult patients with normal renal function. In pediatric patients under 12 years of age, equivalent plasma concentrations are attained by infusing 500 mg/m^2 at a constant rate over at least 1 hour, every 8 hours for 7 days. Obese patients should be dosed at 10 mg/kg (Ideal Body Weight). A maximum dose equivalent to 500 mg/m^2 every 8 hours should not be exceeded for any patient.

Patients with Acute or Chronic Renal Impairment: Refer to DOSAGE AND ADMINISTRATION section for recommended doses, and adjust the dosing interval as indicated in the table below.

Creatinine Clearance (mL/min/1.73 m^2)	Percent of Recommended Dose	Dosing Interval (hours)
>50	100%	8
25–50	100%	12
10–25	100%	24
0–10	50%	24

Hemodialysis: For patients who require dialysis, the mean plasma half-life of acyclovir during hemodialysis is approximately 5 hours. This results in a 60% decrease in plasma concentrations following a 6-hour dialysis period. Therefore, the patient's dosing schedule should be adjusted so that an additional dose is administered after each dialysis.[24,25]

Peritoneal Dialysis: No supplemental dose appears to be necessary after adjustment of the dosing interval.[40, 41]

Method of Preparation: Each 10-mL vial contains acyclovir sodium equivalent to 500 mg of acyclovir. Each 20-mL vial contains acyclovir sodium equivalent to 1000 mg of acyclovir. The contents of the vial should be dissolved in Sterile Water for Injection as follows:

Contents of Vial	Amount of Diluent
500 mg	10 mL
1000 mg	20 mL

The resulting solution in each case contains 50 mg acyclovir per mL (pH approximately 11). Shake the vial well to assure complete dissolution before measuring and transferring each individual dose. DO NOT USE BACTERIOSTATIC WATER FOR INJECTION CONTAINING BENZYL ALCOHOL OR PARABENS.

Administration: The calculated dose should then be removed and added to any appropriate intravenous solution at a volume selected for administration during each 1-hour infusion. Infusion concentrations of approximately 7 mg/mL or lower are recommended. In clinical studies, the average 70-kg adult received between 60 and 150 mL of fluid per dose. Higher concentrations (e.g., 10 mg/mL) may produce phlebitis or inflammation at the injection site upon inadvertent extravasation. Standard, commercially available electrolyte and glucose solutions are suitable for intravenous administration; biologic or colloidal fluids (e.g., blood products, protein solutions, etc.) are not recommended.

Once in solution in the vial at a concentration of 50 mg/mL, the drug should be used within 12 hours. Once diluted for administration, each dose should be used within 24 hours. Refrigeration of reconstituted solutions may result in formation of a precipitate which will redissolve at room temperature.

HOW SUPPLIED

...containing acyclovir sodium equivalent to 500 mg of acyclovir, tray of 10 (NDC 0173-0951-01).

20-mL sterile vials, each containing acyclovir sodium equivalent to 1000 mg of acyclovir, tray of 10 (NDC 0173-0952-01).

Store at 15° to 25°C (59° to 77°F).

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April 1998/RL-543

Shown in Product Identification Guide, page 315

ZYBAN™ B
[zi' ban]
(bupropion hydrochloride)
Sustained-Release Tablets

DESCRIPTION

ZYBAN (bupropion hydrochloride) Sustained-Release Tablets are a non-nicotine aid to smoking cessation. Initially developed and marketed as an antidepressant (WELLBUTRIN® [bupropion hydrochloride] Tablets and WELLBUTRIN® SR [bupropion hydrochloride] Sustained-Release Tablets), ZYBAN is chemically unrelated to tricyclic, tetracyclic, selective serotonin re-uptake inhibitor, or other known antidepressant agents. Its structure closely resembles that of diethylpropion; it is related to phenylethylamines. It is (±)-1-(3-chlorophenyl)-2-[(1,1-dimethylethyl)amino]-1-propanone hydrochloride. The molecular weight is 276.2. The molecular formula is $C_{13}H_{18}ClNO \cdot HCl$. Bupropion hydrochloride powder is white, crystalline, and highly soluble in water. It has a bitter taste and produces the sensation of local anesthesia on the oral mucosa.

ZYBAN is supplied for oral administration as 150-mg (purple), film-coated, sustained-release tablets. Each tablet contains the labeled amount of bupropion hydrochloride and the inactive ingredients carnauba wax, cysteine hydrochloride, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbat

Continued on next page

This product information is based on labeling in effect on Jur 1, 1998. For further information, contact via direct mail, phon or web site Medical Information: Glaxo Wellcome Inc., PO Bc 13398, Research Triangle Park, NC 27709. Healthca Professionals (Medical Information): 800-334-0089 Patien (Customer Response Center): 888-TALK2GW (1-888-825-524 Glaxo Wellcome Corporate Web Site: www.glaxowellcome.co

Table 2: Comparative Trial: Quit Rates by Treatment Group

	Treatment Groups			
Abstinence From Week 4 Through Specified Week	Placebo (n = 160) % (95% CI)	Nicotine Transdermal System (NTS) 21 mg/day (n = 244) % (95% CI)	ZYBAN™ 300 mg/day (n = 244) % (95% CI)	ZYBAN 300 mg/day and NTS 21 mg/day (n = 245) % (95% CI)
Week 7 (4-week quit)	23% (17-30)	36%* (30-42)	49%*† (43-56)	58%*†‡ (51-64)
Week 10	20% (14-26)	32%* (26-37)	46%*† (39-52)	51%*† (45-58)

* $P<0.01$ versus placebo.
† $P<0.01$ versus NTS.
‡ $P = 0.06$ versus ZYBAN.

should not be used. **The seizure rate associated with doses of sustained-release bupropion up to 300 mg/day is approximately 0.1% (1/1,000). This incidence was prospectively determined during an 8-week treatment exposure in approximately 3,100 depressed patients. Data for the immediate-release formulation of bupropion revealed a seizure incidence of approximately 0.4% (4/1,000) in depressed patients treated at doses in a range of 300 to 450 mg/day. In addition, the estimated seizure incidence increases almost tenfold between 450 and 600 mg/day.**

- **Patient factors: Predisposing factors that may increase the risk of seizure with bupropion use include history of head trauma or prior seizure, central nervous system (CNS) tumor, and concomitant medications that lower seizure threshold.**
- **Clinical situations: Circumstances associated with an increased seizure risk include, among others, excessive use of alcohol; abrupt withdrawal from alcohol or other sedatives; addiction to opiates, cocaine, or stimulants; use of over-the-counter stimulants and anorectics; and diabetes treated with oral hypoglycemics or insulin.**
- **Concomitant medications: Many medications (e.g., antipsychotics, antidepressants, theophylline, systemic steroids) and treatment regimens (e.g., abrupt discontinuation of benzodiazepines) are known to lower seizure threshold.**

Recommendations for Reducing the Risk of Seizure: Retrospective analysis of clinical experience gained during the development of bupropion suggests that the risk of seizure may be minimized if

- **the total daily dose of ZYBAN does *not* exceed 300 mg (the maximum recommended dose for smoking cessation); and**
- **the recommended daily dose for most patients (300 mg/day) is administered in divided doses (150 mg twice daily).**
- **No single dose should exceed 150 mg to avoid high peak concentrations of bupropion and/or its metabolites.**
- **ZYBAN should be administered with extreme caution to patients with a history of seizure, cranial trauma, or other predisposition(s) toward seizure, or patients treated with other agents (e.g., antipsychotics, antidepressants, theophylline, systemic steroids, etc.) or treatment regimens (e.g., abrupt discontinuation of a benzodiazepine) that lower seizure threshold.**

Potential for Hepatotoxicity: In rats receiving large doses of bupropion chronically, there was an increase in incidence of hepatic hyperplastic nodules and hepatocellular hypertrophy. In dogs receiving large doses of bupropion chronically, various histologic changes were seen in the liver, and laboratory tests suggesting mild hepatocellular injury were noted.

PRECAUTIONS

General: ***Allergic Reactions:*** Anaphylactoid reactions characterized by symptoms such as pruritus, urticaria, angioedema, and dyspnea requiring medical treatment have been reported at a rate of about 1-3 per thousand in clinical trials of ZYBAN. In addition, there have been rare spontaneous postmarketing reports of erythema multiforme, Stevens-Johnson syndrome, and anaphylactic shock associated with bupropion.

Insomnia: In the dose-response smoking cessation trial, 29% of patients treated with 150 mg/day of ZYBAN and 35% of patients treated with 300 mg/day of ZYBAN experienced insomnia, compared to 21% of placebo-treated patients. Symptoms were sufficiently severe to require discontinuation of treatment in 0.6% of patients treated with ZYBAN and none of the patients treated with placebo.

In the comparative trial, 40% of the patients treated with 300 mg/day of ZYBAN, 28% of the patients treated with 21 mg/day of NTS, and 45% of the patients treated with the combination of ZYBAN and NTS experienced insomnia compared to 18% of placebo-treated patients. Symptoms were sufficiently severe to require discontinuation of treatment in 0.8% of patients treated with ZYBAN and none of the patients in the other three treatment groups.

Insomnia may be minimized by avoiding bedtime doses and, if necessary, reduction in dose.

Psychosis, Confusion, and Other Neuropsychiatric Phenomena: In clinical trials with ZYBAN conducted in non-depressed smokers, the incidence of neuropsychiatric side effects was generally comparable to placebo. Depressed patients treated with bupropion in depression trials have been reported to show a variety of neuropsychiatric signs and symptoms including delusions, hallucinations, psychosis, concentration disturbance, paranoia, and confusion. In some cases, these symptoms abated upon dose reduction and/or withdrawal of treatment.

Activation of Psychosis and/or Mania: Antidepressants can precipitate manic episodes in bipolar disorder patients during the depressed phase of their illness and may activate latent psychosis in other susceptible individuals. The sustained-release formulation of bupropion is expected to pose similar risks. There were no reports of activation of psychosis or mania in clinical trials with ZYBAN conducted in non-depressed smokers.

Use in Patients With Systemic Illness: There is no clinical experience establishing the safety of ZYBAN in patients with a recent history of myocardial infarction or unstable heart disease. Therefore, care should be exercised if it is used in these groups. Bupropion was well tolerated in depressed patients who had previously developed orthostatic hypotension while receiving tricyclic antidepressants, and was generally well tolerated in a group of 36 depressed inpatients with stable CHF. However, bupropion was associated with a rise in supine blood pressure in the study of patients with CHF, resulting in discontinuation of treatment in two patients for exacerbation of baseline hypertension.

In the comparative trial, 6.1% of patients treated with the combination of ZYBAN and NTS had treatment-emergent hypertension compared to 2.5%, 1.6%, and 3.1% of patients treated with ZYBAN, NTS, and placebo, respectively. The majority of these patients had evidence of preexisting hypertension. Three patients (1.2%) treated with the combination of ZYBAN and NTS and one patient (0.4%) treated with NTS had study medication discontinued due to hypertension compared to none of the patients treated with ZYBAN or placebo. Monitoring for treatment-emergent hypertension is recommended in patients receiving the combination of ZYBAN and NTS.

Because bupropion hydrochloride and its metabolites are almost completely excreted through the kidney and metabolites are likely to undergo conjugation in the liver prior to urinary excretion, treatment of patients with renal or hepatic impairment should be initiated at reduced dosage as bupropion and its metabolites may accumulate in such patients to a greater extent than usual. The patient should be closely monitored for possible toxic effects of elevated blood and tissue levels of drug and metabolites.

Information for Patients: See PATIENT INFORMATION at the end of this labeling for the text of the separate leaflet provided for patients. Physicians are advised to review the leaflet with their patients and to emphasize that ZYBAN contains the same active ingredient found in WELLBUTRIN and WELLBUTRIN SR used to treat depression and that ZYBAN should not be used in conjunction with WELLBUTRIN, WELLBUTRIN SR, or any other medications that contain bupropion hydrochloride.

Laboratory Tests: There are no specific laboratory tests recommended.

Drug Interactions: In vitro studies indicate that bupropion is primarily metabolized to hydroxybupropion by the CYP2B6 isoenzyme. Therefore, the potential exists for a drug interaction between ZYBAN and drugs that affect the CYP2B6 isoenzyme metabolism (e.g., orphenadrine and cyclophosphamide). The threohydrobupropion metabolite of bupropion does not appear to be produced by the cytochrome P450 isoenzymes. No systemic data have been collected on the metabolism of ZYBAN following concomitant administration with other drugs or, alternatively, the effect of concomitant administration of ZYBAN on the metabolism of other drugs.

Animal data indicated that bupropion may be an inducer of drug-metabolizing enzymes in humans. However, following chronic administration of bupropion, 100 mg t.i.d. to healthy male volunteers for 14 days, there was no evidence of induction of its own metabolism. Because bupropion is extensively metabolized, the coadministration of other drugs may affect its clinical activity. In particular, certain drugs may induce the metabolism of bupropion (e.g., carbamazepine, phenobarbital, phenytoin), while other drugs may inhibit the metabolism of bupropion (e.g., cimetidine).

Studies in animals demonstrate that the acute toxicity of bupropion is enhanced by the MAO inhibitor phenelzine (see CONTRAINDICATIONS).

Limited clinical data suggest a higher incidence of adverse experiences in patients receiving concurrent administration of bupropion and levodopa. Administration of ZYBAN to patients receiving levodopa concurrently should be undertaken with caution, using small initial doses and gradual dose increases.

Concurrent administration of ZYBAN and agents (e.g., antipsychotics, antidepressants, theophylline, systemic steroids, etc.) or treatment regimens (e.g., abrupt discontinuation of benzodiazepines) that lower seizure threshold should be undertaken only with extreme caution (see WARNINGS).

Physiological changes resulting from smoking cessation itself, with or without treatment with ZYBAN, may alter the pharmacokinetics of some concomitant medications, which may require dosage adjustment.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Lifetime carcinogenicity studies were performed in rats and mice at doses up to 300 and 150 mg/kg per day, respectively. These doses are approximately ten and two times the maximum recommended human dose (MRHD), respectively, on a mg/m^2 basis. In the rat study, there was an increase in nodular proliferative lesions of the liver at doses of 100 to 300 mg/kg per day (approximately three to ten times the MRHD on a mg/m^2 basis); lower doses were not tested. The question of whether or not such lesions may be precursors of neoplasms of the liver is currently unresolved. Similar liver lesions were not seen in the mouse study, and no increase in malignant tumors of the liver and other organs was seen in either study.

Bupropion produced a positive response (two to three times control mutation rate) in two of five strains in the Ames bacterial mutagenicity test and an increase in chromosomal aberrations in one of three in vivo rat bone marrow cytogenetic studies.

A fertility study in rats at doses up to 300 mg/kg revealed no evidence of impaired fertility.

Pregnancy: ***Teratogenic Effects: Pregnancy Category B:*** Reproduction studies have been performed at doses up to 450 mg/kg in rats (approximately 14 times the MRHD on a mg/m^2 basis), and at doses up to 150 mg/kg in rabbits (approximately 10 times the MRHD on a mg/m^2 basis). There is no evidence of impaired fertility or harm to the fetus due to bupropion. There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. Pregnant smokers should be encouraged to attempt cessation using educational and behavioral interventions before pharmacological approaches are used.

To monitor fetal outcomes of pregnant women exposed to ZYBAN, Glaxo Wellcome Inc. maintains a Bupropion Pregnancy Registry. Health care providers are encouraged to register patients by calling (800) 722-9292, ext. 39441.

Labor and Delivery: The effect of ZYBAN on labor and delivery in humans is unknown.

Nursing Mothers: Bupropion and its metabolites are secreted in human milk. Because of the potential for serious adverse reactions in nursing infants from ZYBAN, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: Clinical trials with ZYBAN did not include individuals under the age of 18. Therefore, the safety and efficacy in a pediatric smoking population have not been established. The immediate-release formulation of bupropion

Continued on next page

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ban—Cont.

studied in 104 pediatric patients (age range, 6 to 16) in ical trials of the drug for other indications. Although erally well tolerated, the limited exposure is insufficient sess the safety of bupropion in pediatric patients.

in the Elderly: In general, older patients are known to abolize drugs more slowly and to be more sensitive to side effects of drugs. A single-dose pharmacokinetic y demonstrated that the disposition of bupropion and metabolites in elderly subjects was similar to that of nger subjects (see CLINICAL PHARMACOLOGY). Of approximately 5,600 patients who participated in clinitrials with bupropion sustained-release tablets (depres- and smoking cessation studies), 303 were 60 to 69 years and 88 were 70 years of age or older. The experience patients 60 years of age or older was similar to that in nger patients.

VERSE REACTIONS

also WARNINGS and PRECAUTIONS):

information included under ADVERSE REACTIONS is d primarily on data from the dose-response trial and comparative trial that evaluated ZYBAN for smoking ation (see CLINICAL TRIALS). Information on additi- al adverse events associated with the sustained-release ulation of bupropion in depression trials, as well as the diate-release formulation of bupropion, is included in parate section (see Other Events Observed During the ical Development and Postmarketing Experience of Bupion).

erse Events Associated With the Discontinuation of tment: Adverse events were sufficiently troublesome ause discontinuation of treatment in 8% of the 708 pats treated with ZYBAN and 5% of the 313 patients ted with placebo. The more common events leading to ontinuation of treatment with ZYBAN included nervous tem disturbances (3.4%), primarily tremors, and skin rders (2.4%), primarily rashes.

idence of Commonly Observed Adverse Events: The st commonly observed adverse events consistently asso- ed with the use of ZYBAN were dry mouth and insom- . The most commonly observed adverse events were de- d as those that consistently occurred at a rate of five per- tage points greater than that for placebo across clinical dies.

se Dependency of Adverse Events: The incidence of mouth and insomnia may be related to the dose of BAN. The occurrence of these adverse events may be imized by reducing the dose of ZYBAN. In addition, in- nia may be minimized by avoiding bedtime doses.

verse Events Occurring at an Incidence of 1% or More ong Patients Treated With ZYBAN: Table 3 enumer- s selected treatment-emergent adverse events from the e-response trial that occurred at an incidence of 1% or re and were more common in patients treated with BAN compared to those treated with placebo. Table 4 imerates selected treatment-emergent adverse events m the comparative trial that occurred at an incidence of or more and were more common in patients treated with BAN, NTS, or the combination of ZYBAN and NTS com- red to those treated with placebo. Reported adverse nts were classified using a COSTART-based dictionary.

Table 3: Treatment-Emergent Adverse Event Incidence in the Dose-Response Trial*

Body System/ Adverse Experience	ZYBAN™ 100 to 300 mg/day (n = 461) %	Placebo (n = 150) %
dy (General)		
leck pain	2	<1
llergic reaction	1	0
rdiovascular		
lot flashes	1	0
lypertension	1	<1
gestive		
ry mouth	11	5
ncreased appetite	2	<1
norexia	1	<1
usculoskeletal		
rthralgia	4	3
yalgia	2	1
ervous system		
nsomnia	31	21
izziness	6	7
remor	2	1
somnolence	2	1
hinking abnormality	1	0
espiratory		
ronchitis	2	0
Skin		
Pruritus	3	<1
Rash	3	<1
Dry skin	2	0
Urticaria	1	0
Special senses		
Taste perversion	2	<1

*Selected adverse events with an incidence of at least 1% of patients treated with ZYBAN and more frequent than in the placebo group.

(See table 4 at top of next page)

Other Events Observed During the Clinical Development and Postmarketing Experience of Bupropion: In addition to the adverse events noted above, the following events have been reported in clinical trials with the sustained-release formulation of bupropion in depressed patients and in non-depressed smokers, as well as in clinical trials and postmarketing clinical experience with the immediate-release formulation of bupropion.

Adverse events for which frequencies are provided below occurred in clinical trials with bupropion sustained-release. The frequencies represent the proportion of patients who experienced a treatment-emergent adverse event on at least one occasion in placebo-controlled studies for depression (n=987) or smoking cessation (n=1,013), or patients who experienced an adverse event requiring discontinuation of treatment in an open-label surveillance study with bupropion sustained-release tablets (n=3,100). All treatment-emergent adverse events are included except those listed in Tables 3 and 4, those events listed in other safety-related sections of the insert, those adverse events subsumed under COSTART terms that are either overly general or excessively specified so as to be uninformative, those events not reasonably associated with the use of the drug, and those events that were not serious and occurred in fewer than two patients.

Events are further categorized by body system and listed in order of decreasing frequency according to the following definitions of frequency: Frequent adverse events are defined as those occurring in at least 1/100 patients. Infrequent adverse events are those occurring in 1/100 to 1/1,000 patients, while rare events are those occurring in less than 1/1,000 patients.

Adverse events for which frequencies are not provided occurred in clinical trials or postmarketing experience with the immediate-release formulation of bupropion. Only those adverse events not previously listed for sustained-release bupropion are included. The extent to which these events may be associated with ZYBAN is unknown.

Body (General): Frequent were asthenia, fever, and headache. Infrequent were back pain, chills, inguinal hernia, musculoskeletal chest pain, pain, and photosensitivity. Rare was malaise.

Cardiovascular: Infrequent were flushing, migraine, postural hypotension, stroke, tachycardia, and vasodilation. Rare was syncope. Also observed were cardiovascular disorder, complete AV block, extrasystoles, hypotension, myocardial infarction, phlebitis, and pulmonary embolism.

Digestive: Frequent were dyspepsia, flatulence, and vomiting. Infrequent were abnormal liver function, bruxism, dysphagia, gastric reflux, gingivitis, glossitis, jaundice, and stomatitis. Rare was edema of tongue. Also observed were colitis, esophagitis, gastrointestinal hemorrhage, gum hemorrhage, hepatitis, increased salivation, intestinal perforation, liver damage, pancreatitis, stomach ulcer, and stool abnormality.

Endocrine: Also observed was syndrome of inappropriate antidiuretic hormone.

Hemic and Lymphatic: Infrequent was ecchymosis. Also observed were anemia, leukocytosis, leukopenia, lymphadenopathy, and pancytopenia.

Metabolic and Nutritional: Infrequent were edema, increased weight, and peripheral edema. Also observed was glycosuria.

Musculoskeletal: Infrequent were leg cramps and twitching. Also observed were arthritis and muscle rigidity/fever/rhabdomyolysis.

Nervous System: Frequent were agitation, depression, and irritability. Infrequent were abnormal coordination, CNS stimulation, confusion, decreased libido, decreased memory, depersonalization, emotional lability, hostility, hyperkinesia, hypertonia, hypesthesia, paresthesia, suicidal ideation, and vertigo. Rare were amnesia, ataxia, derealization, and hypomania. Also observed were abnormal electroencephalogram (EEG), akinesia, aphasia, coma, delirium, delusions, dysarthria, dyskinesia, dystonia, euphoria, extrapyramidal syndrome, hypokinesia, increased libido, manic reaction, neuralgia, neuropathy, paranoid reaction, and unmasking tardive dyskinesia.

Respiratory: Rare was bronchospasm. Also observed was pneumonia.

Skin: Frequent was sweating. Infrequent was acne and dry skin. Rare was maculopapular rash. Also observed were angioedema, exfoliative dermatitis, and hirsutism.

Special Senses: Frequent was amblyopia. Infrequent were accommodation abnormality and dry eye. Also observed were deafness, diplopia, and mydriasis.

Urogenital: Frequent was urinary frequency. Infrequent were impotence, polyuria, and urinary urgency. Also observed were abnormal ejaculation, cystitis, dyspareunia, dysuria, gynecomastia, menopause, painful erection, prostate disorder, salpingitis, urinary incontinence, urinary retention, urinary tract disorder, and vaginitis.

DRUG ABUSE AND DEPENDENCE

ZYBAN is likely to have a low abuse potential.

Humans: There have been few reported cases of drug dependence and withdrawal symptoms associated with the immediate-release formulation of bupropion. In human studies of abuse liability, individuals experienced with drugs of abuse reported that bupropion produced a feeling of euphoria and desirability. In these subjects, a single dose of 400 mg (1.33 times the recommended daily dose) of bupropion produced mild amphetamine-like effects compared to placebo on the Morphine-Benzedrine Subscale of the Addiction Research Center Inventories (ARCI), which is indicative of euphorigenic properties and a score intermediate between placebo and amphetamine on the Liking Scale of the ARCI.

Animals: Studies in rodents and primates have shown that bupropion exhibits some pharmacologic actions common to psychostimulants. In rodents, it has been shown to increase locomotor activity, elicit a mild stereotyped behavioral response, and increase rates of responding in several schedule-controlled behavior paradigms. In primate models to assess the positive reinforcing effects of psychoactive drugs, bupropion was self-administered intravenously. In rats, bupropion produced amphetamine- and cocaine-like discriminative stimulus effects in drug discrimination paradigms used to characterize the subjective effects of psychoactive drugs.

The possibility that bupropion may induce dependence should be kept in mind when evaluating the desirability of including the drug in smoking cessation programs of individual patients.

OVERDOSAGE

Human Overdose Experience: There has been very limited experience with overdosage of the sustained-release formulation of bupropion; three such cases were reported during clinical trials in depressed patients. One patient ingested 3,000 mg of bupropion sustained-release tablets and vomited quickly after the overdose; the patient experienced blurred vision and lightheadedness. A second patient ingested a "handful" of bupropion sustained-release tablets and experienced confusion, lethargy, nausea, jitteriness, and seizure. A third patient ingested 3,600 mg of bupropion sustained-release tablets and a bottle of wine; the patient experienced nausea, visual hallucinations, and "grogginess." None of the patients experienced further sequelae. There has been extensive experience with overdosages of the immediate-release formulation of bupropion. Thirteen overdoses occurred during clinical trials in depressed patients. Twelve patients ingested 850 to 4,200 mg and recovered without significant sequelae. Another patient who ingested 9,000 mg of the immediate-release formulation of bupropion and 300 mg of tranylcypromine experienced a grand mal seizure and recovered without further sequelae.

Since introduction, overdoses of up to 17,500 mg of the immediate-release formulation of bupropion have been reported. Seizure was reported in approximately one third of all cases. Other serious reactions reported with overdoses of the immediate-release formulation of bupropion alone included hallucinations, loss of consciousness, and sinus tachycardia. Fever, muscle rigidity, rhabdomyolysis, hypotension, stupor, coma, and respiratory failure have been reported when the immediate-release formulation of bupropion was part of multiple drug overdoses.

Although most patients recovered without sequelae, deaths associated with overdoses of the immediate-release formulation of bupropion alone have been reported rarely in patients ingesting massive doses of the drug. Multiple uncontrolled seizures, bradycardia, cardiac failure, and cardiac arrest prior to death were reported in these patients.

Management of Overdose: Following suspected overdose, hospitalization is advised. If the patient is conscious, vomiting should be induced by syrup of ipecac. Activated charcoal also may be administered every 6 hours during the first 12 hours after ingestion. Baseline laboratory values should be obtained. Electrocardiogram and EEG monitoring also are recommended for the next 48 hours. Adequate fluid intake should be provided.

If the patient is stuporous, comatose, or convulsing, airway intubation is recommended prior to undertaking gastric lavage. Although there is little clinical experience with lavage following an overdose of bupropion, it is likely to be of benefit within the first 12 hours after ingestion since absorption of the drug may not yet be complete.

Table 4: Treatment-Emergent Adverse Event Incidence in the Comparative Trial*

Adverse Experience (COSTART Term)	ZYBAN™ 300 mg/day (n = 243) %	Nicotine Transdermal System (NTS) 21 mg/day (n = 243) %	ZYBAN and NTS (n = 244) %	Placebo (n = 159) %
Body				
Abdominal pain	3	4	1	1
Accidental injury	2	2	1	1
Chest pain	<1	1	3	1
Neck pain	2	1	<1	0
Facial edema	<1	0	1	0
Cardiovascular				
Hypertension	1	<1	2	0
Palpitations	2	0	1	0
Digestive				
Nausea	9	7	11	4
Dry mouth	10	4	9	4
Constipation	8	4	9	3
Diarrhea	4	4	3	1
Anorexia	3	1	5	1
Mouth ulcer	2	1	1	1
Thirst	<1	<1	2	0
Musculoskeletal				
Myalgia	4	3	5	3
Arthralgia	5	3	3	2
Nervous system				
Insomnia	40	28	45	18
Dream abnormality	5	18	13	3
Anxiety	8	6	9	6
Disturbed concentration	9	3	9	4
Dizziness	10	2	8	6
Nervousness	4	<1	2	2
Tremor	1	<1	2	0
Dysphoria	<1	1	2	1
Respiratory				
Rhinitis	12	11	9	8
Increased cough	3	5	<1	1
Pharyngitis	3	2	3	0
Sinusitis	2	2	2	1
Dyspnea	1	0	2	1
Epistaxis	2	1	1	0
Skin				
Application site reaction†	11	17	15	7
Rash	4	3	3	2
Pruritus	3	1	5	1
Urticaria	2	0	2	0
Special Senses				
Taste perversion	3	1	3	2
Tinnitus	1	0	<1	0

*Selected adverse events with an incidence of at least 1% of patients treated with either ZYBAN, NTS, or the combination of ZYBAN and NTS and more frequent than in the placebo group.
†Patients randomized to ZYBAN or placebo received placebo patches.

While diuresis, dialysis, or hemoperfusion are sometimes used to treat drug overdosage, there is no experience with their use in the management of overdoses of bupropion. Because diffusion of bupropion and its metabolites from tissue to plasma may be slow, dialysis may be of minimal benefit. Based on studies in animals, it is recommended that seizures be treated with an intravenous benzodiazepine preparation and other supportive measures, as appropriate. Further information about the treatment of overdoses may be available from a poison control center.

DOSAGE AND ADMINISTRATION

ZYBAN: ***Usual Dosage for Adults:*** The recommended and maximum dose of ZYBAN is 300 mg/day, given as 150 mg twice daily. Dosing should begin at 150 mg/day given every day for the first 3 days, followed by a dose increase for most patients to the recommended usual dose of 300 mg/day. There should be an interval of at least 8 hours between successive doses. Doses above 300 mg/day should not be used (see WARNINGS). Treatment with ZYBAN should be initiated while the patient is still smoking, since approximately 1 week of treatment is required to achieve steady-state blood levels of bupropion. Patients should set a "target quit date" within the first 2 weeks of treatment with ZYBAN, generally in the second week. Treatment with ZYBAN should be continued for 7 to 12 weeks; duration of treatment should be based on the relative benefits and risks for individual patients. If a patient has not made significant progress towards abstinence by the seventh week of therapy with ZYBAN, it is unlikely that he or she will quit during that attempt, and treatment should probably be discontinued. Dose tapering of ZYBAN is not required when discontinuing treatment. It is important that patients continue to receive counseling and support throughout treatment with ZYBAN, and for a period of time thereafter.

Individualization of Therapy: Patients are more likely to quit smoking and remain abstinent if they are seen frequently and receive support from their physicians or other health care professionals. It is important to ensure that patients read the instructions provided to them and have their questions answered. Physicians should review the patient's overall smoking cessation program that includes treatment with ZYBAN. Patients should be advised of the importance of participating in the behavioral interventions, counseling, and/or support services to be used in conjunction with ZYBAN. See information for patients at the end of the package insert.

The goal of therapy with ZYBAN is complete abstinence. If a patient has not made significant progress towards abstinence by the seventh week of therapy with ZYBAN, it is unlikely that he or she will quit during that attempt, and treatment should be discontinued.

Patients who fail to quit smoking during an attempt may benefit from interventions to improve their chances for success on subsequent attempts. Patients who are unsuccessful should be evaluated to determine why they failed. A new quit attempt should be encouraged when factors that contributed to failure can be eliminated or reduced, and conditions are more favorable.

Maintenance: Although clinical data are not available regarding the long-term use (>12 weeks) of bupropion for smoking cessation, bupropion has been used for longer periods of time in the treatment of depression. Whether to continue treatment with ZYBAN for periods longer than 12 weeks for smoking cessation must be determined for individual patients.

Combination Treatment With ZYBAN and a Nicotine Transdermal System (NTS): Combination treatment with ZYBAN and NTS may be prescribed for smoking cessation. The prescriber should review the complete prescribing information for both ZYBAN and NTS before using comb
tion treatment. See also CLINICAL TRIALS for met
and dosing used in the ZYBAN and NTS combination t
Monitoring for treatment-emergent hypertension in
tients treated with the combination of ZYBAN and NT
recommended.

HOW SUPPLIED

ZYBAN Sustained-Release Tablets, 150 mg of bupropion
drochloride, are purple, round, biconvex, film-coated tat
printed with "ZYBAN 150" in bottles of 60 (NDC 0173-0
02) tablets and the ZYBAN Advantage Pack™ containi
bottle of 60 (NDC 0173-0556-01) tablets.
**Store at controlled room temperature, 20° to 25°C (68
77°F) (see USP). Dispense in tight, light-resistant cont
ers as defined in the USP.**

PATIENT INFORMATION: The following wordin
contained in a separate leaflet provided for patients.

Information for the Patient

**ZYBAN™ (bupropion hydrochloride) Sustained-Rele
Tablets**

Please read this information before you start tak
ZYBAN. Also read this leaflet each time you renew your
scription, in case anything has changed. This informatio
not intended to take the place of discussions between
and your doctor. You and your doctor should discuss ZYB
as part of your plan to stop smoking. Your doctor has
scribed ZYBAN for your use only. Do not let anyone else
your ZYBAN.

IMPORTANT WARNING:

There is a chance that approximately 1 out of every 1,
people taking bupropion hydrochloride, the active ingr
ent in ZYBAN, will have a seizure. The chance of this h
pening increases if you:

- have a seizure disorder (for example, epilepsy);
- have or have had an eating disorder (for example, bulir
or anorexia nervosa);
- take more than the recommended amount of ZYBAN;
- take other medicines with the same active ingredient t
is in ZYBAN, such as WELLBUTRIN® (bupropion hyd
chloride) Tablets and WELLBUTRIN® SR (bupropion
drochloride) Sustained-Release Tablets. (Both of th
medicines are used to treat depression.)

You can reduce the chance of experiencing a seizure by
lowing your doctor's directions on how to take ZYBAN.
should also discuss with your doctor whether ZYBAN
right for you.

1. What is ZYBAN?

ZYBAN is a prescription medicine to help people quit sm
ing. Studies have shown that more than one third of peo
quit smoking for at least 1 month while taking ZYBAN a
participating in a patient support program. For many
tients, ZYBAN reduces withdrawal symptoms and the u
to smoke. ZYBAN should be used with a patient supp
program. It is important to participate in the behavio
program, counseling, or other support program your hea
care professional recommends.

2. Who should not take ZYBAN?

You should not take ZYBAN if you:

- have a seizure disorder (for example, epilepsy).
- are already taking WELLBUTRIN, WELLBUTRIN SR,
any other medicines that contain bupropion hydroch
ride.
- have or have had an eating disorder (for example, bulir
or anorexia nervosa).
- are currently taking or have recently taken a monoami
oxidase inhibitor (MAOI).
- are allergic to bupropion.

3. Are there special concerns for women?

ZYBAN is not recommended for women who are pregnant
breast-feeding. Women should notify their doctor if they
come pregnant or intend to become pregnant while taki
ZYBAN.

4. How should I take ZYBAN?

- You should take ZYBAN as directed by your doctor. T
usual recommended dosing is to take one 150-mg tablet
the morning for the first 3 days. On the fourth day, beg
taking one 150-mg tablet in the morning and one 150-m
tablet in the early evening. Doses should be taken at lea
8 hours apart.
- **Never take an "extra" dose of ZYBAN.** If you forget
take a dose, do not take an extra tablet to "catch up" f
the dose you forgot. Wait and take your next tablet at t
regular time. Do not take more tablets than your doct
prescribed. This is important so you do not increase yo
chance of having a seizure.
- It is important to swallow ZYBAN Tablets whole. Do n
chew, divide, or crush tablets.

Continued on next page

**This product information is based on labeling in effect on Ju
1, 1998. For further information, contact via direct mail, phon
or web site Medical Information: Glaxo Wellcome Inc., PO B
13398, Research Triangle Park, NC 27709. Healthca
Professionals (Medical Information): 800-334-0089 Patien
(Customer Response Center): 888-TALK2GW (1-888-825-524
Glaxo Wellcome Corporate Web Site: www.glaxowellcome.co**

yban—Cont.

How long should I take ZYBAN?
ost people should take ZYBAN for 7 to 12 weeks. Follow ur doctor's instructions.

When should I stop smoking?
takes about 1 week for ZYBAN to reach the right levels in ur body to be effective. So, to maximize your chance of itting, you should not stop smoking until you have been king ZYBAN for 1 week. You should set a date to stop ioking during the second week you're taking ZYBAN.

Can I smoke while taking ZYBAN?
is not physically dangerous to smoke and use ZYBAN at e same time. However, continuing to smoke after the date u set to stop smoking will seriously reduce your chance of eaking your smoking habit.

Can ZYBAN be used at the same time as nicotine patches?
s, ZYBAN and nicotine patches can be used at the same ne but should only be used together under the supervision your doctor. Using ZYBAN and nicotine patches together ay raise your blood pressure. Your doctor will probably ant to check your blood pressure regularly to make sure at it stays within acceptable levels.
O NOT SMOKE AT ANY TIME if you are using a nicotine itch or any other nicotine product along with ZYBAN. It is ssible to get too much nicotine and have serious side efcts.

What are possible side effects of ZYBAN?
ke all medicines, ZYBAN may cause side effects.
The most common side effects include dry mouth and difficulty sleeping. These side effects are generally mild and often disappear after a few weeks. If you have difficulty sleeping, avoid taking your medicine too close to bedtime.
The most common side effects that caused people to stop taking ZYBAN during clinical studies were shakiness and skin rash.
Contact your doctor or health care professional if you have a rash or other troublesome side effects.
Use caution before driving a car or operating complex, hazardous machinery until you know if ZYBAN affects your ability to perform these tasks.

Can I drink alcohol while I am taking ZYBAN?
is best to not drink alcohol at all or to drink very little hile taking ZYBAN. If you drink a lot of alcohol and suddenly stop, you may increase your chance of having a seiire. Therefore, it is important to discuss your use of alcool with your doctor before you begin taking ZYBAN.

I. Will ZYBAN affect other medicines I am taking?
YBAN may affect other medicines you're taking. It is imortant not to take medicines that may increase the chance r you to have a seizure. Therefore, you should make sure iat your doctor knows about all medicines—prescription or ver-the-counter—you are taking or plan to take.

2. Do ZYBAN Tablets have a characteristic odor?
YBAN Tablets may have a characteristic odor. If present, iis odor is normal.

3. How should I store ZYBAN?
Store ZYBAN at room temperature, out of direct sunlight.
Keep ZYBAN in a tightly closed container.
Keep ZYBAN out of the reach of children.

his summary provides important information about YBAN. This summary cannot replace the more detailed inrmation that you need from your doctor. If you have any uestions or concerns about either ZYBAN or smoking cesation, talk to your doctor or other health care professional.

HABITROL is a registered trademark of Ciba-Geigy Corporation.

eptember 1997/RL-448

Shown in Product Identification Guide, page 315

ZYLOPRIM® ℞
[zī ′lō-prim]
(allopurinol)
100 mg Scored Tablets and
300 mg Scored Tablets

DESCRIPTION

ZYLOPRIM (allopurinol) is known chemically as 1,5-dihydro-4*H*-pyrazolo[3,4-*d*]pyrimidin-4-one. It is a xanthine oxidase inhibitor which is administered orally. Each scored white tablet contains 100 mg allopurinol and the inactive ingredients lactose, magnesium stearate, potato starch, and povidone. Each scored peach tablet contains 300 mg allopurinol and the inactive ingredients corn starch, FD&C Yellow No. 6 Lake, lactose, magnesium stearate, and povidone. Its solubility in water at 37°C is 80.0 mg/dL and is greater in an alkaline solution.

CLINICAL PHARMACOLOGY

ZYLOPRIM acts on purine catabolism, without disrupting the biosynthesis of purines. It reduces the production of uric acid by inhibiting the biochemical reactions immediately preceding its formation.

ZYLOPRIM is a structural analogue of the natural purine base, hypoxanthine. It is an inhibitor of xanthine oxidase, the enzyme responsible for the conversion of hypoxanthine to xanthine and of xanthine to uric acid, the end product of purine metabolism in man. ZYLOPRIM is metabolized to the corresponding xanthine analogue, oxipurinol (alloxanthine), which also is an inhibitor of xanthine oxidase.

It has been shown that reutilization of both hypoxanthine and xanthine for nucleotide and nucleic acid synthesis is markedly enhanced when their oxidations are inhibited by ZYLOPRIM and oxipurinol. This reutilization does not disrupt normal nucleic acid anabolism, however, because feedback inhibition is an integral part of purine biosynthesis. As a result of xanthine oxidase inhibition, the serum concentration of hypoxanthine plus xanthine in patients receiving ZYLOPRIM for treatment of hyperuricemia is usually in the range of 0.3 to 0.4 mg/dL compared to a normal level of approximately 0.15 mg/dL. A maximum of 0.9 mg/dL of these oxypurines has been reported when the serum urate was lowered to less than 2 mg/dL by high doses of ZYLOPRIM. These values are far below the saturation levels at which point their precipitation would be expected to occur (above 7 mg/dL).

The renal clearance of hypoxanthine and xanthine is at least 10 times greater than that of uric acid. The increased xanthine and hypoxanthine in the urine have not been accompanied by problems of nephrolithiasis. Xanthine crystalluria has been reported in only three patients. Two of the patients had Lesch-Nyhan syndrome, which is characterized by excessive uric acid production combined with a deficiency of the enzyme, hypoxanthineguanine phosphoribosyltransferase (HGPRTase). This enzyme is required for the conversion of hypoxanthine, xanthine, and guanine to their respective nucleotides. The third patient had lymphosarcoma and produced an extremely large amount of uric acid because of rapid cell lysis during chemotherapy.

ZYLOPRIM is approximately 90% absorbed from the gastrointestinal tract. Peak plasma levels generally occur at 1.5 hours and 4.5 hours for ZYLOPRIM and oxipurinol respectively, and after a single oral dose of 300 mg ZYLOPRIM, maximum plasma levels of about 3 mcg/mL of ZYLOPRIM and 6.5 mcg/mL of oxipurinol are produced.

Approximately 20% of the ingested ZYLOPRIM is excreted in the feces. Because of its rapid oxidation to oxipurinol and a renal clearance rate approximately that of glomerular filtration rate, ZYLOPRIM has a plasma half-life of about 1 to 2 hours. Oxipurinol, however, has a longer plasma half-life (approximately 15 hours) and therefore effective xanthine oxidase inhibition is maintained over a 24-hour period with single daily doses of ZYLOPRIM. Whereas ZYLOPRIM is cleared essentially by glomerular filtration, oxipurinol is reabsorbed in the kidney tubules in a manner similar to the reabsorption of uric acid.

The clearance of oxipurinol is increased by uricosuric drugs, and as a consequence, the addition of a uricosuric agent reduces to some degree the inhibition of xanthine oxidase by oxipurinol and increases to some degree the urinary excretion of uric acid. In practice, the net effect of such combined therapy may be useful in some patients in achieving minimum serum uric acid levels provided the total urinary uric acid load does not exceed the competence of the patient's renal function.

Hyperuricemia may be primary, as in gout, or secondary to diseases such as acute and chronic leukemia, polycythemia vera, multiple myeloma, and psoriasis. It may occur with the use of diuretic agents, during renal dialysis, in the presence of renal damage, during starvation or reducing diets, and in the treatment of neoplastic disease where rapid resolution of tissue masses may occur. Asymptomatic hyperuricemia is not an indication for treatment with ZYLOPRIM (see INDICATIONS AND USAGE).

Gout is a metabolic disorder which is characterized by hyperuricemia and resultant deposition of monosodium urate in the tissues, particularly the joints and kidneys. The etiology of this hyperuricemia is the overproduction of uric acid in relation to the patient's ability to excrete it. If progressive deposition of urates is to be arrested or reversed, it is necessary to reduce the serum uric acid level below the saturation point to suppress urate precipitation.

Administration of ZYLOPRIM generally results in a fall in both serum and urinary uric acid within 2 to 3 days. The degree of this decrease can be manipulated almost at will since it is dose-dependent. A week or more of treatment with ZYLOPRIM may be required before its full effects are manifested; likewise, uric acid may return to pretreatment levels slowly (usually after a period of 7 to 10 days following cessation of therapy). This reflects primarily the accumulation and slow clearance of oxipurinol. In some patients a dramatic fall in urinary uric acid excretion may not occur, particularly in those with severe tophaceous gout. It has been postulated that this may be due to the mobilization of urate from tissue deposits as the serum uric acid level begins to fall.

The action of ZYLOPRIM differs from that of uricosuric agents, which lower the serum uric acid level by increasing urinary excretion of uric acid. ZYLOPRIM reduces both the serum and urinary uric acid levels by inhibiting the formation of uric acid. The use of ZYLOPRIM to block the formation of urates avoids the hazard of increased renal excretion of uric acid posed by uricosuric drugs.

ZYLOPRIM can substantially reduce serum and urinary uric acid levels in previously refractory patients even in the presence of renal damage serious enough to render uricosuric drugs virtually ineffective. Salicylates may be given conjointly for their antirheumatic effect without compromising the action of ZYLOPRIM. This is in contrast to the nullifying effect of salicylates on uricosuric drugs.

ZYLOPRIM also inhibits the enzymatic oxidation of mercaptopurine, the sulfur-containing analogue of hypoxanthine, to 6-thiouric acid. This oxidation, which is catalyzed by xanthine oxidase, inactivates mercaptopurine. Hence, the inhibition of such oxidation by ZYLOPRIM may result in as much as a 75% reduction in the therapeutic dose requirement of mercaptopurine when the two compounds are given together.

INDICATIONS AND USAGE

THIS IS NOT AN INNOCUOUS DRUG. IT IS NOT RECOMMENDED FOR THE TREATMENT OF ASYMPTOMATIC HYPERURICEMIA.

ZYLOPRIM reduces serum and urinary uric acid concentrations. Its use should be individualized for each patient and requires an understanding of its mode of action and pharmacokinetics (see CLINICAL PHARMACOLOGY, CONTRAINDICATIONS, WARNINGS and PRECAUTIONS).

ZYLOPRIM is indicated in:
(1) the management of patients with signs and symptoms of primary or secondary gout (acute attacks, tophi, joint destruction, uric acid lithiasis and/or nephropathy).
(2) the management of patients with leukemia, lymphoma and malignancies who are receiving cancer therapy which causes elevations of serum and urinary uric acid levels. Treatment with ZYLOPRIM should be discontinued when the potential for overproduction of uric acid is no longer present.
(3) the management of patients with recurrent calcium oxalate calculi whose daily uric acid excretion exceeds 800 mg/day in male patients and 750 mg/day in female patients. Therapy in such patients should be carefully assessed initially and reassessed periodically to determine in each case that treatment is beneficial and that the benefits outweigh the risks.

CONTRAINDICATIONS

Patients who have developed a severe reaction to ZYLOPRIM should not be restarted on the drug.

WARNINGS

ZYLOPRIM SHOULD BE DISCONTINUED AT THE FIRST APPEARANCE OF SKIN RASH OR OTHER SIGNS WHICH MAY INDICATE AN ALLERGIC REACTION. In some instances a skin rash may be followed by more severe hypersensitivity reactions such as exfoliative, urticarial, and purpuric lesions as well as Stevens-Johnson syndrome (erythema multiforme exudativum), and/or generalized vasculitis, irreversible hepatotoxicity and on rare occasions death.

In patients receiving PURINETHOL® (mercaptopurine) or IMURAN® (azathioprine), the concomitant administration of 300 to 600 mg of ZYLOPRIM per day will require a reduction in dose to approximately one-third to one-fourth of the usual dose of mercaptopurine or azathioprine. Subsequent adjustment of doses of mercaptopurine or azathioprine should be made on the basis of therapeutic response and the appearance of toxic effects (see CLINICAL PHARMACOLOGY).

A few cases of reversible clinical hepatotoxicity have been noted in patients taking ZYLOPRIM, and in some patients, asymptomatic rises in serum alkaline phosphatase or serum transaminase have been observed. If anorexia, weight loss, or pruritus develop in patients on ZYLOPRIM, evaluation of liver function should be part of their diagnostic workup. In patients with pre-existing liver disease, periodic liver function tests are recommended during the early stages of therapy.

Due to the occasional occurrence of drowsiness, patients should be alerted to the need for due precaution when engaging in activities where alertness is mandatory.

The occurrence of hypersensitivity reactions to ZYLOPRIM may be increased in patients with decreased renal function receiving thiazides and ZYLOPRIM concurrently. For this reason, in this clinical setting, such combinations should be administered with caution and patients should be observed closely.

PRECAUTIONS

General: An increase in acute attacks of gout has been reported during the early stages of administration of

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/427,447	10/27/1999	ALEXANDER GOEN SZYNALSKI		3197

7590 12/04/2001

MARK POHL
55 MADISON AVENUE, 4TH FLOOR
MORRISTOWN, NJ 07960

EXAMINER
RIMELL, SAMUEL G

ART UNIT	PAPER NUMBER
2166	

DATE MAILED: 12/04/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/427,447	SZYNALSKI, ALEXANDER GOEN	
	Examiner	Art Unit	
	Sam Rimell	2166	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P riod f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1,11 and 21-24 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1, 11 and 21-24 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Sam Rimell
Primary Examiner
AU 2166

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claims 1, 11 and 21-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1 and 11 have been amended to recite the usage of an "anti-smoking drug" instead of the originally recited "Lobelia".

The term "anti-smoking drug" broader in scope than the recitations of Lobelia found in the disclosure. Since the term "anti-smoking drug" can encompass prescription pharmaceuticals, it is far broader in scope than the recitation of Lobelia found in the disclosure.

Claims 1 and 11 can be corrected by deploying the term "Lobelia". This may be accomplished by Examiner's Amendment, with applicant's authorization.

Claim 1, 11 and 21-24 would be allowable if rewritten or amended to overcome the rejection under 35 U.S.C. 112, first paragraph, set forth in this Office action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to Sam Rimell at telephone number (703) 306-5626.

Sam Rimell
Primary Examiner
Art Unit 2166

Interview Summary

Application No.	Applicant(s)	
09/427,447	SZYNALSKI, ALEXANDER GOEN	
Examiner	**Art Unit**	
Sam Rimell	2166	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Sam Rimell*. (3)_____.

(2) *Mark Pohl*. (4)_____.

Date of Interview: *14 December 2001* .

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☐ No.
If Yes, brief description: _____ .

Claim(s) discussed: _____ .

Identification of prior art discussed: _____ .

Agreement with respect to the claims f)☒ was reached. g)☐ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *Agreed to Examiner's Amendment to place application in condition for allowance* .

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

i)☐ It is not necessary for applicant to provide a separate record of the substance of the interview(if box is checked).

Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

Notice of Allowability

Application No.	Applicant(s)	
09/427,447	SZYNALSKI, ALEXANDER GOEN	
Examiner	**Art Unit**	
Sam Rimell	2166	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *Interview of 12/14/01*.
2. ☒ The allowed claim(s) is/are *1 and 11*.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____.
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
   (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirem nts not d below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

8. ☐ CORRECTED DRAWINGS must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No. ____.
   (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
   (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachm nt(s)

1☒ Notic of References Cited (PTO-892)
3☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
5☐ Information Disclosure Statements (PTO-1449), Paper No. ____.
7☐ Examiner's Comment Regarding Requirement for Deposit of Biological Mat rial
2☐ Notice of Informal Patent Application (PTO-152)
4☒ Interview Summary (PTO-413), Paper No.____ .
6☒ Examiner's Amendment/Comment
8☒ Examiner's Statement of Reasons for Allowance
9☐ Other

SAM RIMELL
PRIMARY EXAM
AU 2166

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mark Pohl on 12/14/01.

In claim 1: In part C, change "an anti-smoking drug" to --lobelia--.

In claim 11: In part C, change "an anti-smoking drug" to --lobelia--.

Claims 21-24: These claims are cancelled.

Terminal Disclaimer

The present application includes a terminal disclaimer which appears to have been mis-directed to this application. The terminal disclaimer has been refused entry for the present application and will be transferred to a continuation application of the present case. No terminal disclaimer has been required for this application.

Reasons for Allowance

The present application includes two independent claims, 1 and 11. The closest prior art are the US Patents 5,414,005 to Schneider et al. and 5,055,478 to Cooper et al.

Schneider et al. differs from both claims 1 and 11 in that it does not disclose the usage of an educational program in combination with the usage of lobelia. Schneider et al. is primarily addressed to a sublingual form of lobelia with certain specified advantages.

Copper et al. differs from both claims 1 and 11 in that it does not disclose the combination of a non-conditioning educational program, a hypnosis program and lobelia administration.

Any inquiry concerning this communication should be directed to Sam Rimell at telephone number (703) 306-5626.

Sam Rimell
Primary Examiner
Art Unit 2166

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/427,447	10/27/1999	ALEXANDER GOEN SZYNALSKI		3197

7590 02/04/2002

MARK POHL
55 MADISON AVENUE, 4TH FLOOR
MORRISTOWN, NJ 07960

EXAMINER
RIMELL, SAMUEL G

ART UNIT	PAPER NUMBER
2166	

DATE MAILED: 02/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

corrected **Notice of Allowability**	Applicati n No. 09/427,447	Applicant(s) SZYNALSKI, ALEXANDER GOEN	
	Examiner Sam Rimell	Art Unit 2166	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due cours . **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiativ of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to _____.
2. ☒ The allowed claim(s) is/are *1, 6, 11, 16*.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from th International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
   (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

8. ☐ CORRECTED DRAWINGS must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
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   (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
   (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

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4☐ Interview Summary (PTO-413), Paper No.____ .
6☐ Examiner's Amendment/Comment
8☐ Examiner's Statement of Reasons for Allowance
9☐ Other

Sam Rimell
Primary Examiner
Art Unit: 2166

US006431874B1

(12) **United States Patent**
Szynalski

(10) **Patent No.: US 6,431,874 B1**
(45) **Date of Patent: Aug. 13, 2002**

(54) **STOP SMOKING METHOD AND COMPOSITION**

(75) Inventor: **Alexander Goen Szynalski**, Randolph, NJ (US)

(73) Assignee: **Goen Corporation**, Cedar Knolls, NJ (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/427,447**

(22) Filed: **Oct. 27, 1999**

(51) **Int. Cl.**[7] **G09B 23/28**
(52) **U.S. Cl.** **434/262**
(58) **Field of Search** 514/282, 343; 424/449; 434/262

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,055,478 A * 10/1991 Cooper et al. 514/343
5,414,005 A * 5/1995 Schneider et al. 514/343
5,780,051 A * 7/1998 Eswara et al. 424/449
5,965,567 A * 10/1999 Archer et al. 514/282

FOREIGN PATENT DOCUMENTS

GB 1017032 1/1966

* cited by examiner

Primary Examiner—Sam Rimell
(74) *Attorney, Agent, or Firm*—Pharmaceutical Patent Law, LLC; Mark Pohl

(57) **ABSTRACT**

The inventor discloses a unique, new and useful process to reduce tobacco smoking, entitled Stop Smoking Method and Composition, consisting of: (1) educating tobacco smokers regarding smoking, its physiological dangers and addictive nature, and techniques to stop smoking; (2) hypnotizing said tobacco smokers, and (3) providing dietary substances to address the nutritional needs of nicotine addiction and the nutritional challenges thereof.

8 Claims, No Drawings

STOP SMOKING METHOD AND COMPOSITION

BACKGROUND

The prior art discloses many stop-smoking products and methods including, for example; (A) education to educate smokers regarding smoking, its physiological dangers and addictive nature, and conscious techniques to stop smoking; (B) hypnosis, to use the unconscious mind to stop smoking; and (C) nutritional supplements, addressing the nutritional challenges with regard to stopping smoking.

SUMMARY

While using each one of these three elements is known in the art, I have found that by combining all of these three elements together, they act on the three areas most important for stopping smoking—the conscious mind, the unconscious mind, and the body—and are synergistically effective in helping people to stop smoking.

This synergy was unexpected. I am a Certified Hypnotist and am a Nutritionist, with over twenty years experience in the fields of hypnosis, seminar presentation and nutrition. I am a member of the American Association of Professional Hypnotherapists, the National Guild of Hypnotists, the International Association of Counselors and Therapists, and am certified by the Hypnodyne Foundation. I am listed in *Who's Who in Executives and Professionals*, and I was a finalist for the 1999 Ernst & Young Entrepreneur of the Year award. I have been a special guest on numerous national television and radio programs, and was featured on the #1 television fitness show in the country. I maintain a practice in Cedar Knolls, N.J. I have successfully used hypnosis in many types of situations. I have, for example, worked with athletes to improve their athletic performance, and have worked with corporations as a sales and personal-development trainer. I am driven by a sincere passion for helping people maximize their personal potential and overcome addictions to smoking and food. I enjoy a reputation for extremely high success through my seminars.

DETAILED DESCRIPTION

My invention therefore comprises three elements: (1) education for the conscious mind regarding smoking, its physiological dangers and addictive nature, and techniques to stop smoking; (2) hypnosis for the unconscious mind, which hypnosis addresses the unconscious mind and its way of affecting behavior; and (3) dietary substances, to address the physiological needs of a person entailed in stopping smoking.

Education. The first element of my invention is education regarding smoking. This educational process can include addressing the benefits of a regular exercise program. Thus, the educational materials or program educates the smoker to engage in some form of light exercise. Not only will exercise help clear the body of the toxins acquired through smoking, but exercise will also help release endorphins which relieve stress as well as making you feel good. Exercise will rapidly reverse the damage done to the body from smoking. If the smoker has not engaged in exercise for a long time, or the smoker has a weight problem or any other health problem, the smoker should consult their physician before starting any regimen of exercise.

In addition to this, I have found that in my preferred embodiment of my invention, the education program also addresses the physiological progression of smoking, its physiological dangers and addictive nature, and some conscious techniques to stop smoking. ©1999

The physiological progression of smoking entails three discreet steps. Knowing these steps helps the smoker recognize them as they occur, and thus recognize the needs they fill.

Stage 1—Light a cigarette and inhale. This takes about 7 seconds. The deep breath of the inhale increases the flow of blood and oxygen to the heart and you feel more relaxed (not due to the cigarette, but due to the deep breath).

Stage 2—Seven seconds to fifteen minutes later, nicotine enters the liver, which in turn releases sugar into the bloodstream. This results in a physical uplift (not from the cigarette, but from the release of sugar into the bloodstream) which then in turn causes the pancreas to release insulin into the bloodstream. This gives you an energy boost. Normally, it is a temporary energy boost because the muscle cells of the body are resistant to insulin. So what happens is that your energy level goes up and then crashes, all over again. In fifteen minutes, you want to start smoking again due to the tense feelings you experience from your energy level being reduced. What we suggest is for you to sensitize your body to insulin. Before we suggest how you do this, you first should study the two diagrams pictured below. To better understand this phenomenon, we will provide an in-depth clarification of the diagrams.

Stage 3—Fifteen to twenty minutes after beginning to smoke, the nicotine interrupts the normal transmission of neurons by competing with acetylcholine at the nerve terminal, producing such effects as an increased heart rate and respiration, along with feelings of tension and of being "wired up." It also increases arousal and a sense of well-being and focused attention. A side benefit to understanding this step is to take proper nutrients so you do not allow this physical and physiological progression of smoking to occur. This will help with maintaining or even reducing weight and increasing lean muscle tissue.

In my preferred embodiment, the smoker is educated on the physiological dangers and addictive nature of smoking. These dangers are now so widely known as to not need to be discussed in detail here.

In my preferred embodiment, the person is educated on the benefits of modifying their daily diet. This addresses potential weight gain problems, one of the biggest fears of smokers.

Regarding potential weight gain, why do we gain weight when we stop smoking? Muscle cells become more sensitive to insulin. In my preferred embodiment, therefore, I recommend:

Avoid refined carbohydrates. All carbohydrates start out in their rarest edible form as complex, but we make them refined by processing, preserving, storing, drying, and cooking.

Increase physical activity, especially five to fifteen minutes after meals.

Take 100 micrograms of chromium along with the proper cofactors, one half hour before each meal with a full glass of water. The product containing chromium (CHROMIUM CHELAVITE™) that I prefer is TRIMSPA®, available from Vitamerica, Inc., Cedar Knolls, N.J.

Acquire a cigarette cessation product containing the herb lobelia, which aids any withdrawal that some may experience. Lobelia is a natural herb that tricks the body into thinking it is nicotine, but it does not have the side effects. In the preferred embodiment of my invention, I recommend CIGSATION™, available from Vitamerica, Inc., Cedar Knolls, N.J.

Cut back on drinking coffee and other caffeinated beverages. Sometimes the stress or anxiety that quitters experience is due to the physiological effects of caffeine on the nervous system and not due to withdrawal from nicotine. Try drinking decaffeinated tea or some other warm decaffeinated beverage. Drinking a hot tea provides the same psychological effect as drinking hot coffee.

Eat healthy, nourishing, non-processed foods and take a good vitamin supplement. Remember, the 200+ toxins in cigarette smoke have helped deplete the body of vitamins. Five cigarettes can deplete all the vitamin C in the body! By eating a healthy diet, you will recover your health more quickly.

In my preferred embodiment, the smoker is educated to do this for at least the first week, preferably for the first 21 days, after stopping smoking:

Eat 3 meals a day, including breakfast

Have protein and complex carbohydrates with each meal

Avoid sugar

Drink 8 glasses of non-caloric liquids a day—drink water with lemon, seltzer, herbal tea, etc.

Keep a pitcher of water on your desk and you'll easily drink 8 glasses a day

Between meals, drink fruit juices or eat a piece of fruit

Eat lots of fruits, vegetables and salads

As soon as you finish eating, leave the table and go brush your teeth

Use mouthwash whenever possible

In my preferred embodiment, the smoker is admonished: to not skip any meals (and never miss breakfast); to limit refined-sugar intake (and read packaging labels); to avoid beverages with caffeine (tea, colas, coffee, hot chocolate); and, if you must have them, drink tea or coffee out of a juice glass using a straw; and NO alcohol.

We described above the change in blood sugar levels caused by smoking and the physical and emotional response it has on the body. If your blood sugar level gets low, you will either crave a cigarette or something sweet. In either case, it will boost your blood sugar level for 10 to 20 minutes and then cause a crash, triggering another urge for a cigarette or a sweet. By eating 3 meals a day, you will tend to have a stable blood sugar level, and this minimizes cigarette and eating urges. Eating protein with carbohydrates at breakfast sets the stage for stable blood sugar levels all through the day. Protein with complex carbohydrates stabilizes the blood sugar.

I have also found it useful to teach persons quitting smoking to carry a nonfood item such as a swizzle stick or a low calorie food such as celery or carrot sticks. Use these to gratify any oral habit that has been developed by the conditioned response of putting your hand to your mouth 250 times a day, as if you were a one pack a day smoker.

By providing the smoker with this kind of educational program, the smoker is able to consciously and analytically understand their need to smoke and to approach the decision to smoke, or to not smoke, in an analytical, dispassionate manner.

Hypnosis. In addition to the conscious, analytical mind, one can aid the stop-smoking process by using the subconscious mind. In my invention, it is important to use both the conscious mind—via the educational program discussed above—and the unconscious mind, with hypnosis.

The subconscious mind dominates your thinking and behaviors. It is programmed using repetition and the subconscious mind basically behaves for two reasons. It tries to take you towards pleasure and it wants you to stay away from pain. For example, when you have a cup of coffee, you grab a cigarette; you get into a car, you grab a cigarette; you get stuck at a light, you grab a cigarette; you get a break at work, you grab a cigarette; you have a cocktail, you grab a cigarette. If you do not experience these triggers, you may very often go many hours without having a cigarette. It is important that you identify these scenes so we can then break the connection of the cigarettes to the scenes.

With hypnosis, the subconscious mind no longer aids the body to smoke more often, but rather aids the body to stop smoking, during precisely those periods when a smoker is accustomed to having a cigarette. Instead of the subconscious making the body scream for nicotine after a meal, or with coffee or alcohol, the subconscious will help the smoker remain calm and pain free.

When used to stop smoking, I have found that in my preferred embodiment, the hypnosis focuses on interrupting "conditioned responses" generally, and specifically, on interrupting the response to smoke. Conditioned responses are actions (e.g., reaching for a cigarette) motivated not by a consciously-perceived need, but rather by unconscious habit.

Is smoking more of a physical or more of a psychological addiction? For example, how many times have you gone two, three or four hours without even smoking one cigarette and then in another hour you may smoke four, five or six cigarettes? Why is that? It is because certain events, or certain times of the day can trigger you to smoke a cigarette. Therefore, it is necessary to break these unconscious connections, and such breakage occurs, I found, most efficiently using unconscious means—hypnosis.

In my preferred embodiment of my invention, the hypnosis is done in-person and is reinforced later with prerecorded media such as audio-tapes.

Hypnosis techniques are known in the art. In my preferred embodiment, I prefer the in-person hypnosis to follow a six-step protocol. The six steps are (1) neuro-linguistic programming, (2) physical positioning, (3) progressive relaxation, (4) occupying the critical/analytical factor, (5) a process of suggestion, and (6) changing the language of the subconscious.

(1) Neuro-linguistic programming is a technique known in the art. It is described in detail in the following works written since the 1960's.

The Structure of Magic, Vol.1—Richard Bandler/John Grinder

The Structure of Magic, Vol.2—Grinder/Bandler

Patterns of Hypnotic Techniques of M. H. Erickson, Vol.1 Bandler/Grinder

Patterns of Hypnotic Techniques of M. H. Erickson, Vol.2 Grinder/Bandler

Frogs Into Princes—Bandler/Grinder

Tranceformations—Grinder/Bandler

Using Your Brain for a Change—Richard Bandler
Time for a Change—Richard Bandler
Persuasion Engineering—Richard Bandler/John La Valle
The Adventures of Anybody—Richard Bandler
Science and Sanity—Alfred Korzybski
Uncommon Therapy—The Psychiatric Techniques of Erickson—Jay Haley
Training Trances—John Overdurf/Julie Silverthorn
My Voice Will Go With You—Sidney Rosen These are incorporated herein by reference.

(2) Physical positioning is important, to maintain the subject in a state which is both relaxed, yet not sleep-prone.

(3) Physical Positioning and Progressive Relaxation follow the methods known in the art, instructing the subject to progressively relax each part of their body. This can be done with instructions to, for example, physically perform some act, or to mentally visualize some relaxing phenomenon.

(4) Occupying the critical/analytical factor is accomplished in my preferred embodiment by having the subject perform certain tasks which both require some conscious attention, but also are not so difficult or complex as to absorb the subject's entire mental capacity.

(5) The process of suggestion is important to repeat for an effective period of time—usually at least daily for about twenty one days. This time may, however, be less when the subject is relaxed, or is in a highly-emotional state.

(6) The last step is changing the language of the subconscious. This is done by repeating a desired message—e.g., "I am free from smoking"—often enough that the desired message replaces an undesired message in the subconscious mind. For example, one technique is to get friends, coworkers, and family members to help you, by asking them to congratulate you for not smoking. The best way to accomplish this is to stick your hand out to a friend or family member, asking that person to shake your hand and congratulate you for being a nonsmoker. When that person congratulates you, it is a positive reinforcement. The (former) smoker benefits from this positive feedback, and from knowing that they are doing well in stopping smoking.

In another technique I found successful, smoking is described as like having a best friend. Psychologically, the cigarette is the support that a friend gives you. Imagine having your best friend there for you and then losing him or her. You would not feel very good losing your best friend. However, if you discover that your best friend was abusing your children, most likely you would not feel the same about losing your best friend. You would still have some sort of attachment, but now you would be able to reason your way out of not having this person as a friend. In my preferred embodiment, the educational program teaches smokers to look at smoking in the same way.

In my preferred embodiment of my invention, hypnosis is also administered by listening to a prerecorded audio script which provides stop-smoking messages and positive feedback for not smoking. Such audio tapes are commercially available. In my preferred embodiment, I use an audio tape titled "Smoking Cessation," published by Vitamerica, Inc. Cedar Knolls, N.J., www.vitamerica.com, to be listened to once every day for an effective length of time, generally about twenty-one days.

Dietary Substances. The third element of my invention is using proper dietary substances. These address the physiological needs of people breaking their physical addiction to nicotine. Further, one of the biggest fears of smokers is that, in stopping smoking, they will gain excess weight. Thus, in my preferred embodiment, in addition to the dietary substances that support normal form and function while recovering from a smoking addiction, one also uses dietary substances that support normal form and function for those seeking weight-loss or to reduce weight gain. In my preferred embodiment, I recommend CIGSATION™ and TRIM SPECIFICS™, dietary supplements by Vitamerica, Inc., Cedar Knolls, N.J., www.vitamerica.com.

To aid the reader's understanding, I will discuss first the biological basis of the smoking addiction. I will then discuss the dietary substances and the diet modifications I have found effective to combat the physical smoking addiction—the addiction to nicotine. Finally, I will discuss dietary substances to control weight gain.

What causes the addiction to nicotine? The nervous system is divided into two anatomical divisions. The first is the central nervous system, which is composed of the brain and spinal cord. The second is the peripheral nervous system, which includes neurons located outside the brain and spinal cord, which includes any nerves that enter or leave the central nervous system. The peripheral nervous system can be further divided into the efferent division, whose neurons carry signals away from the brain and spinal cord to the peripheral tissues, and the afferent division, whose neurons bring information from the periphery to the central nervous system.

Nerve impulses are transmitted along a path of cells called neurons. The neurons form a knot-like mass called ganglia. These neurons are connected by a series of bridges. The bridge is called a synapse. In order to dross the bridge, a neurotransmitter is required. Before the nerve impulses reach the relay station or bridge, they are referred to a pre-ganglionic neurons. After crossing the synapse, they are referred to as post-ganglionic neurons. The basic neurotransmitters of the autonomic nervous system are acetylcholine and epinephrine. Acetylcholine mediates the transmission of nerve impulses across autonomic ganglia in both the sympathetic and parasympathetic nervous systems.

Nicotine Receptors. These receptors, in addition to binding acetylcholine, also recognize nicotine. Nicotine initially stimulates and then blocks the receptor. There is a competitive inhibition taking place. In lay terms, the receptor has a greater affinity for nicotine than for acetylcholine. At the same time, nicotine increases the level of the neurotransmitter dopamine in a particular brain pathway which associates a molecular link between nicotine addiction and this pleasure producing pathway. This is why nicotine causes such as strong physiological addiction. Recently, scientists at Yale and at the Pasteur Institute in Paris have found that the beta 2 sub unit of a known nicotine receptor in the brain is a critical component in nicotine addiction.

To combat this nicotine addiction, it is useful to use lobelia. *Lobelia inflata* (also known as Indian Tobacco) is a plant. This plant contains three nicotine-like ingredients : 1) lobeline, 2) lobelanidine, and 3) lobelanine. On close inspection of these three ingredients one can notice that all are symmetrical molecules. In other words, if you cut them each in half, each half is the same. The only exception is with lobeline, which has a slight difference on one side of the molecule. I refer to each of these three compounds, their analogs, and derivatives, as "lobelia." After explaining some basic physiology, you will see why lobelia is important.

Nicotine causes an increase in blood pressure, increases intestinal motility, stimulates the central nervous system, has an anti diuretic effect (ability to retain water), affects heart rate, affects respiration, is highly soluble and crosses the blood-brain barrier, produces some euphoria (feeling of well being), arousal, relaxation, and it improves attention, and crosses the placenta membrane and is secreted in the milk of

lactating women. The chronic effects of Nicotine include nasopharyngeal and bronchial irritation, lung cancer, cardiac irregularities, stimulated salivary secretion, and reduction of gastric acidity.

Let us now consider the structural formulas for the active constituents in lobelia. Because of their basically symmetrical structure, it appears that they have an advantage in competing with nicotine at the effector cell site. It is postulated that these components can attach themselves to the cell site from either side of the molecule and perhaps crowd out the nicotine. Later, after the nicotine is eliminated from the system, lobeline will replace nicotine at the effector cell site. While nicotine is rapidly eliminated from the body within 16–24 hours, the withdrawal symptoms can last for several weeks to several months, depending upon the individual.

Lobelia's action in the body mimics that of nicotine, but does not have the physiological dependence of nicotine. Lobelia exhibits a cross tolerance with nicotine, is one of the most useful systemic relaxants, has a relaxation effect on the central nervous system, has a relaxing action on the autonomic nervous system, has a general relaxing action on neuromuscular action, is a powerful respiratory stimulant, equalizes circulation and relieves vascular tension, provides a truly holistic action with a combination of stimulation and relaxation, and also provides the holistic action of a general relaxant with diffusive stimulation.

Recently, scientists in Japan have discovered an antidepressant component in the leaves of *lobelia inflata*. This probably explains why individuals feel better when taking lobelia.

Given this physiology, the physiologic needs of a smoker can be addressed using lobelia. In addition to lobelia, I have found that other herbal substances are useful as dietary substances. Thus, in my preferred embodiment, lobelia is used along with wood betony, fennel seed and licorice root and several other herbs. In addition to these vitamin-type nutritional supplements, in my invention one needs lobelia. Lobelia is also known as Indian tobacco or wild tobacco and is native to North America. It includes three components significant here: lobeline, lobelanidine and lobelanine. It is pharmacologically similar to nicotine, but does not have nicotine's physiological dependency.

In my preferred embodiment of my invention, I have found it beneficial to include certain other supplements derived from plants and herbs. Each the individual ingredients improves the function of lobelia alone, as each provides a specific function to enhance the efficacy of the product.

Wood Betony. Wood betony is used for its sedative and bitter properties. Its anti-hypertensive properties relieve nervous tension and dilate blood vessels, thus producing a calming effect. Wood betony can relieve headaches normally associated with nicotine withdrawal. Its bitter tonic properties also aid in nicotine withdrawal.

Fennel Seed. Fennel seed has been recognized to have carminative and stimulant properties. It has been reported to have a spasmolytic effect on smooth muscles. As a result, it can be used for dyspeptic discomfort, gastrointestinal discomforts and congestion of the upper respiratory tract. Since chain smokers normally have a smoker's cough resulting in congestion of the lungs, fennel seed can aid in treating that congestion. One of the constituents from the volatile oil expressed from fennel is anethol. Anethol has been shown experimentally to reduce secretions of the upper respiratory tract (i.e., lungs).

Licorice Root. The major active ingredient in licorice root is glycyrrhizin. The glycyrrhizin is responsible for a vasopressor response, which is similar to that occurring in nicotine. However, while it mimics that response, it also exhibits anti-inflammatory and an antitussive effects that is comparable to codeine in potency. This is due to the derivative 18 Beta-glycyrrhetinic acid which prevents smoker's cough. In addition, the flavonoids in licorice root have recently been shown to have strong antioxidant and anti-hepatotoxic activities. These activities will help cleanse the body of the free radicals and other toxic substances generated from smoking. Licorice extracts are often used in anti-smoking preparations as a flavoring agent to mask bitter nauseous or other undesirable tastes from other components of the preparation. Licorice can also be used to treat stomach irritation arising from nicotine usage.

In addition to the foregoing, I have found it useful to use also blue cohosh, black walnut husk, chamomile flower, gotu kola leaf extract, kava kava root, peppermint, sarsaparilla root, slippery elm bark, valerian root, bayberry fruit, myrrh, passion flower, ginger root and eucalyptus oil. Thus, in my preferred embodiment, I use each of these, for the following reasons.

Blue Cohosh. It has demonstrated anti-inflammatory activity in animals. Blue cohosh can be used for nervous disorders. .

Black Walnut Husk. Black walnut husk is a blood cleanser and oxidizer. It has been shown to be useful in lung disease and has strong anti-fungal and antibacterial properties. It is a rich dietary source of protein, iodine, chromium, potassium, manganese, vitamin A and the powerful antioxidant vitamin C.

Chamomile Flower. Chamomile flower has essential oils that contain a variety of glycosides, and other important constituents and chemically related compounds. Several of the therapeutic constituents of the volatile oil are chamazulene and alpha bisabolol oxide A. Chamazulene has demonstrated anti-inflammatory activity, pain relieving, wound healing, antispasmodic and anti-microbial properties. Alpha bisabolol has anti-inflammatory, anti-microbial and anti-peptic activities. Matricin has been found to have a sufficiently stronger anti-inflammatory effect than chamazulene.

Gotu Kola Leaf Extract. The gotu kola leaves contain properties that have been shown to accelerate wound healing, improve memory, relieve fatigue and stress, increase mental acuity and improve behavioral patterns. This produces a calming effect within the body, thereby relieving the stress associated with nicotine withdrawal symptoms.

Kava Kava Root. The active ingredients in kava kava root are a group of compounds known as the kavalactones. They are recognized for their biological activity as a sedative, anti-convulsive and tonic. Additional constituents in kava kava root have demonstrated muscle relaxant activity and have been used for their ability to combat nervous anxiety and unrest. Kava kava also has expectorant properties. This allows the heavy smoker to expectorate residual mucus from the lungs.

Peppermint. Peppermint yields a volatile oil that is composed mainly of menthol. Menthol has long been recognized as a cooling agent in topical preparations. Also present are many other ingredients, some of which have been characterized to have biological activity. One such constituent is bisabolene, which has demonstrated to have anti-inflammatory activity. Other constituents in peppermint include flavonoids such as hesperetin and rutin. Also present are tocopherols, carotenoids, choline and azulenes. Azulene isolated from peppermint demonstrated anti-inflammatory and antinuclear effects in experimental animals. Peppermint

oil is extensively used as a flavoring agent, carminative, antiseptic and local anesthetic in cold, cough and other preparations. Peppermint and their oils have been used in traditional medicine as a stomachic, stimulant, antiseptic, local anesthetic and antispasmodic in treating indigestion, sore throat, nausea, diarrhea and colds.

Sarsaparilla Root. The major component of sarsaparilla is a variety of steroids which include sarsasapogenin, smilagenin, sitosterol, stigmasterol and pollinastanol, and their glycosides (saponins) including sarsasaponin (parillin), smilasaponin (smilacin), sarsaparilloside and sitosterol glucoside. Sarsaparilla is reported to have hepatoprotective, diuretic and anti-inflammatory activity.

Slippery Elm Bark. The principal constituent of slippery elm bark is mucilage. The mucilage has demulcent (soothing) and nutritive properties. It can sometimes be used to soothe irritated lungs.

Valerian Root. Valerian root has a variety of constituents but the major one, valerenic acid, produces a nerving or sedative effect. Valerian has CNS depressant activities. As a result, in states of agitation normally witnessed by smokers during withdrawal, this will have a calming effect. It has also been shown that in conditions of fatigue, the herb has demonstrated stimulating properties.

Bayberry Fruit. Bayberry fruit has been recognized to have a tonic effect.

Myrrh. Myrrh is reported to have astringent effects on mucus membranes. It is often used as a flavor component to mask bitter ingredients. It has also been used as a stimulant and expectorant. The expectorant properties will help the smoker remove mucus and phlegm from the lungs.

Passion Flower. Passion flower contains indole alkaloids, flavonoids and steroids. The indole alkaloids and flavonoids have tranquilizing effects. Anxiolytic and hypotensive activity has also been reported.

Ginger Root. Ginger root is used to combat nausea and vomiting, which may accompany nicotine withdrawal.

Eucalyptus Leaf Oil. The leaves contain 0.05 to 3.5% oil. The oil consists mostly of eucalyptol (1, 8-cineole). It is used in an anti-smoking formula as an expectorant to help remove mucus from the lungs.

In my preferred embodiment of my invention, these dietary substances are used as found in CIGSATION™ 100% Natural Cigarette Replacement System, commercially available from Vitamerica, Inc., Cedar Knolls, N.J. 07927, www.vitamerica.com. Each of these dietary substances adds to the benefit obtained from using lobelia alone.

In addition to addressing the physical nicotine addiction, I find it useful to address the smoker's fear of excessive weight gain, by using a "weight control product," a drug or dietary substances useful in controlling unnatural weight gain. Such dietary substances include chromium, choline, inositol, vanadium, gynema sylvestre, lecithin, vitamin B6, ginseng, zinc, mahuang, kola nut extract, spirulina, and methionine. Several of these are known physiological stimulants, which increase thermogenesis in the body and thus promote expending calories. I will discuss each in turn, and its usefulness in a weight-control product.

Chromium. What is chromium? It's the mineral that no body can afford to be without. Like iron, copper and zinc, chromium is one of the 16 essential trace minerals the body needs to keep healthy and fit. And for people who are overweight and out of shape, chromium may be the most precious mineral of all. In its biologically active form, it helps insulin to metabolize fat, convert protein into muscle, and convert sugar into energy. Chromium-activated insulin actually increases almost twenty times the amount of glucose available for energy production, optimizing energy output so that you feel healthy and alive.

Chromium is the "master" nutrient for controlling blood sugar. It helps overcome sugar cravings, which is a problem with many overweight people. It also plays an important role in controlling blood lipids, lowering harmful LDL cholesterol, and increasing beneficial HDL cholesterol.

Research shows that a chromium deficiency may be a widespread problem. Many people, such as athletes, diabetics, mothers and the elderly, are at especially high risk. A lack of chromium can impair insulin function, thereby inhibiting protein synthesis and energy production. More seriously, it can even lead to type II diabetes and heart disease.

In my preferred embodiment, the chromium is a form of chromium commercially available under the trade name CHROMIUM CHELAVITE™, available from Vitamerica, Inc. of Cedar Knolls, N.J.

The most biologically active form of chromium, the true GTF chromium, is the basis for the molecular structure of CHROMIUM CHELAVITE™. Studies on CHROMIUM CHELAVITE™ at a leading Utah university have shown that this form of chromium is clearly superior to both chromium picolinate and chromium polynicotinate in absorb ability. It had an absorption rate that was 53% greater than for chromium picolinate and 91% greater than that observed for chromium polynicotinate.

Choline. Choline is one of the most beneficial nutritional supplements. Technically, it is not a vitamin, even though it is essential for human life. There are three major functions of choline among humans. It is needed for building cell structure, it prevents or minimizes unhealthy fat deposits in the liver, and it acts as a precursor to acetylcholine. Acetylcholine is a neurotransmitter in the brain which is responsible for nerve impulses, memory, learning, mood elevation and depression control.

Choline has a very positive effect on the health of the liver. It is a lipotropic agent (fat eliminator) that can cut away fats in the liver to be used instead of energy. Choline aids in weight loss by facilitating Growth Hormone (GH) releasers, controlling cholesterol, and helping control the appetite. It also helps reduce the "gut transit time", the amount of time it takes food to move through the intestines. In addition to helping speed food through the system, choline also plays an important role in the body's ability to metabolize fat and cholesterol.

Inositol. Inositol is a member of the B complex of vitamins. It provides a calming effect, nourishes brain cells, helps reduce cholesterol, slows artery hardening, prevents eczema, and is needed for hair growth and metabolism. It is found in high concentrations in the brain, and serves as a brain cell membrane stabilizer. Inositol also helps in lecithin formation, and aids the body in the metabolism of fat and cholesterol.

Vanadium. A trace mineral like chromium, vanadium is essential for cellular activity and for the formation of bones and teeth. It also inhibits the synthesis of cholesterol and lowers certain forms of high blood pressure. It works remarkably well as a powerful insulin mimic and has been shown to normalize blood sugar levels, even in diabetics.

Gynema Sylvestre. This tropical herb is beginning to receive much attention due to impressive results in recent studies. Gynema Sylvestre appears to have a positive effect in lowering blood sugar levels, especially in diabetics. Research also suggests that it can help curb sugar absorption.

Lecithin. Lecithin is part of every single cell in the body, but has its greatest concentration in the brain. About 17–20%

of the brain is made up from lecithin. Lecithin is an emulsifier. It is used in the manufacture of chocolate, because it keeps it liquid and it keeps it moving. Lecithin does the same thing for the fat in the human body; it keeps it moving, right out of the body.

Lecithin is a natural diuretic and an effective cholesterol reducer. It helps prevent the buildup of cholesterol on arterial walls, thus improving the circulation of the blood. One study that examined 900 men for atherosclerosis (fat deposits in the arteries) showed that those with more than 36% lecithin in the blood had no atherosclerosis. Those with less than 34% showed evidence of the disease.

Lecithin is also the source of two of the hardest to find B-Complex relatives, choline and inositol. A major function of lecithin is to supply choline in the diet. Choline (see entry) has the function of breaking down fat deposits in the body. Our bodies do not manufacture enough choline. Therefore, we must rely upon our food and supplements such as lecithin to make sure that we get enough.

Vitamin B6. Vitamin B6 aids in more bodily functions than any other single nutrient. It facilitates the body's use of carbohydrates, proteins and fats. It promotes mental performance by aiding in the transport of amino acids, which are used by the brain to increase mental energy and memory. It also promotes the transport of choline, and aids in the breakdown of glycogen, the primary fuel for the brain.

Ginseng. For centuries, the Chinese have testified to the beneficial effects of Ginseng on longevity. Ginseng provides stimulation to the entire body, helping to overcome stress and fatigue. Ginseng can regulate and normalize blood pressure and blood sugar levels. It has been called a cure-all and has also been claimed to be a mild sexual stimulant. Over all, Ginseng has a phenomenal effect on the body's energy level.

Zinc. Zinc is another important trace mineral that is used by more than 200 enzymes to keep the body's major metabolic systems going strong. In addition to its role in metabolism, zinc is a potent antioxidant, profoundly important in enhancing the immune system, stimulating cellular growth, reducing excess levels of damaging free radicals, and improving general health.

Mahuang. Mahuang, also known as ephedra, contains a potent alkaloid, ephedrine. This natural stimulant increases the basal metabolic rate, which helps to burn calories more effectively. It has also been used as a remedy for kidney and bladder problems, as well as for colds, asthma, and hay fever.

Kola Nut Extract. This is a natural stimulant that increases energy and stamina. It has been found to be very useful in preventing fatigue. Kola Nut Extract also acts as a tonic agent for the heart, and it is sometimes useful in relieving pain, neuralgia, and headache.

Spirulina. This famed blue-green algae contains concentrations of nutrients unlike any other single grain, plant or herb. This super nutrient is a naturally digestible food that aids in protecting the immune system, in cholesterol reduction and in mineral absorption. It also helps to cleanse and heal, while also curbing the appetite.

Methionine. Methionine is an amino acid that assists the gall bladder function by helping to synthesize bile salts. It is a lipotropic substance that prevents the deposits of and cohesion of fats in the liver. It is also reported to be a growth hormone releaser.

It serves as an antioxidant in the brain. It helps prevent the buildup of heavy metals and plays an important and essential role in the production of the brain neurotransmitter choline. Methionine is not found in the body. Therefore, it must be gotten via food and supplementation. It is also a good source of sulfur, and its therapeutic lipotropic effects help to eliminate fatty substances from the body.

Each of these dietary substances can be found in TRIM SPECIFICS™, available from Vitamerica, Cedar Knolls, N.J., www.vitamerica.com.

Without further elaboration, it is believed that one skilled in the art can, using the preceding description, utilize the present invention to is fullest extent. The examples I discuss here are included as the preferred embodiment of my invention, and not to further qualify the description.

I claim:

1. A method for helping a tobacco smoker to stop smoking, said method comprising the steps of:

(A) providing to a tobacco smoker a non-conditioning, educational program to educate said tobacco smoker's conscious mind, said educational program including education both on the disadvantages of smoking and on conscious techniques to stop smoking,

(B) providing to said tobacco smoker at least one hypnosis program to train said tobacco smoker's subconscious mind to discourage said tobacco smoker from performing smoking behavior, and

(C) providing to said tobacco smoker an anti-smoking drug in an amount effective to aid in the reduction or cessation of said tobacco smoker's craving to smoke tobacco,

such that said tobacco smoker can be helped to stop smoking.

2. The method of claim 1, where said hypnosis program comprises prerecorded media useable by said tobacco smoker when alone.

3. A product to aid a tobacco smoker in ceasing to smoke tobacco, said product comprising:

(A) means for educating said tobacco smoker's conscious mind, said educational program including non-conditioning education both on the disadvantages of smoking and on conscious techniques to stop smoking,

(B) means for hypnosis to train said tobacco smoker's subconscious mind to discourage said tobacco smoker from performing smoking behavior, and

(C) an anti-smoking drug in an amount effective to aid in the reduction or cessation of said tobacco smoker's craving to smoke tobacco.

4. The product of claim 3, where said means for hypnosis comprises prerecorded media useable by said tobacco smoker when alone.

5. The method of claim 1, further comprising the step of: (D) providing to said tobacco smoker, at least one weight-control product, in an amount effective to aid in weight control.

6. The method of claim 5, where the weight control product includes at least one stimulant in an amount effective to aid in weight control.

7. The product of claim 3, further comprising: (D) at least one weight-control product in an amount effective to aid in weight control.

8. The product of claim 7, where the weight control product includes at least one stimulant in an amount effective to aid weight control.

* * * * *

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

A. GOEN SEMINARS INSTITUTE, INC.,

Plaintiff,

v.

GORAYEB SEMINARS, INC., GORAYEB NUTRITIONAL PRODUCTS INC., and RONALD B. GORAYEB,

Defendants

Civ. 03-1051(KSH)

GORAYEB SEMINARS, INC., GORAYEB NUTRITIONAL PRODUCTS, INC., and RONALD B. GORAYEB,

Counterclaim Plaintiffs

v.

A. GOEN SEMINARS INSTITUTE, INC., GOEN TECHNOLOGIES, INC., NUTRAMERICA CORPORATION, VITAMERICA CORPORATION, GOEN GROUP, GOEN CORPORATION, WALTER SZYNALSKI, and ALEXANDER GOEN SZYNALSKI,

Counterclaim Defendants.

ANSWER AND COUNTERCLAIMS

AFFIRMATIVE DEFENSES

22. U.S. Patent No. 6,431,874 is invalid for patent applicant's failure to comply with 35 USC §§ 101; 102; 103; and 112.

23. U.S. Patent No. 6,431,874 is not infringed under 34 USC §271 by any activities or products of the defendants-counterclaim plaintiffs.

24. U.S. Patent No. 6,431,874 is unenforceable due to plaintiff's misuse of the same and/or, upon information and belief, due to patent applicant's inequitable conduct before the U.S. Patent and Trademark Office, and/or due to plaintiff's attempt to enforce the false claims of the printed patent, which plaintiff knows were never granted, and/or due to the submission to the court, by way of Exhibit A to the Complaint, of a document known by plaintiff to contain false claims due to substantive printing errors, which document and its import were mischaracterized in the complaint.

AS AND FOR DEFENDANTS' COUNTERCLAIMS

Counterclaim plaintiffs Gorayeb Seminars, Inc., Gorayeb Nutritional Products, Inc. and Ronald B. Gorayeb, through their attorneys, allege as follows:

Preliminary Statement

25. The defendants-counterclaim plaintiffs (hereafter collectively "Gorayeb") are direct competitors of the plaintiffs-counterclaim defendants (hereafter collectively "Goen") and have been damaged in an amount yet to be determined by the illegal and tortious conduct of Goen. In brief, Goen obtained U.S. patent '874 for a purported

Please type a plus sign (+) inside this box

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	10/023,254
Filing Date	17 Dec. 2002
First Named Inventor	Alex. G. SZYNALSKI
Group Art Unit	2166
Examiner Name	
Total Number of Pages in This Submission: 11	Attorney Docket Number: Goen

ENCLOSURES *(check all that apply)*

- ☐ Fee Transmittal Form
- ☐ Fee Attached
- ☑ Amendment / Reply
- ☐ After Final
- ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
- ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Assignment Papers *(for an Application)*
- ☐ Drawing(s)
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- ☐ CD, Number of CD(s) one
- ☐ After Allowance Communication to Group
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to Group *(Appeal Notice, Brief, Reply Brief)*
- ☐ Proprietary Information
- ☐ Status Letter
- ☐ Other Enclosure(s) *(please identify below)*:

Remarks

Preliminary amendment, including clean and amended copies of claims. The application has not yet been examined.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	Mark POHL, Reg.35,325, Pharmaceutical Patent Attorneys
Signature	
Date	See below date

CERTIFICATE OF MAILING

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IN THE UNITED STATES PATENT OFFICE

Inventor:	Alexander Goen SZYNALSKI
Serial No.:	10/023,254
Filing Date:	17 Dec. 2001
Title:	*Stop Smoking Method and Composition*
Group Art:	2166
Examiner:	unknown

PRELIMINARY AMENDMENT

A. In the Claims

Please amend the claims as shown on the attached sheets. Enclosed are sheets showing both (1) the amendments to the claims (additions in underline, deletions in strike-through), and (2) clean copies of the claims as amended.

REMARKS

The amendments contained here are not made to overcome any prior art, and do not narrow the scope of the claims; to the contrary, they broaden the coverage of the claims to encompass subject matter disclosed in the Specification but not yet claimed.

To avoid confusion (*e.g.*, to prevent the inadvertent withdraw by the Office of claims not intended to be withdrawn), the attached sheets include all pending claims, including both amended claims and claims not amended.

SUMMARY

Applicant respectfully believes the application is in condition for prompt examination and allowance.

Respectfully submitted,

Mark Pohl, Reg. No. 35,325
7 November 2002

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X:\PTO Forms\Prelim Amendment.doc

CLAIMS AS AMENDED

1. A method for helping a subject to stop smoking, said method comprising:

(A) providing a non-conditioning educational program to educate the conscious mind to discourage smoking behavior;

(B) providing a hypnosis program to train the subconscious mind to discourage smoking behavior; and

(C) providing a ~~stop-smoking~~ substance selected from the group consisting of : a stop-smoking substance in an amount effective to aid in the reduction or cessation of a craving to smoke tobacco; a weight control substance in an amount effective to control body weight; and a dietary supplement substance in an amount effective to supplement the diet.

2. The method of claim 1, wherein said ~~stop-smoking~~ substance comprises ~~an anti-depressant~~a stop-smoking substance in an amount effective to aid in the reduction or cessation of a craving to smoke tobacco.

3. The method of claim ~~2~~1, wherein said ~~anti-depressant~~substance comprises ~~a drug substance~~a weight control substance in an amount effective to control body weight.

4. The method of claim ~~3~~2, wherein said ~~drug~~ stop-smoking substance comprises buproprion hydrochloride.

5. The method of claim ~~2~~1, wherein said ~~anti-depressant~~substance comprises a ~~nutritional~~dietary supplement substance in an amount effective to supplement the diet.

6. The method of claim ~~5~~1, wherein said ~~nutritional supplement~~substance comprises gotu kola.

7. The method of claim ~~5~~1, wherein said ~~nutritional supplement~~substance comprises kava kava.

8. The method of claim ~~5~~1, wherein said ~~nutritional supplement~~substance comprises lobelia.

9. The method of claim 1, wherein said ~~stop-smoking~~ substance comprises an anxiolytic.

10. The method of claim 9, wherein said anxiolytic ~~comprises~~ is a drug ~~substance~~.

11. The method of claim 9, wherein said anxiolytic ~~comprises~~ is a ~~nutritional~~dietary supplement.

12. The method of claim 1, wherein said ~~stop-smoking~~ substance ~~comprises~~ is a nicotine receptor antagonist.

13. The method of claim 12, wherein said nicotine receptor antagonist ~~comprises~~ is a drug ~~substance~~.

14. The method of claim 12, wherein said nicotine receptor antagonist ~~comprises~~ is a ~~nutritional~~dietary supplement.

15. The method of claim 14, wherein said ~~nutritional~~dietary supplement ~~comprises~~ is lobelia.

16. A system for helping a subject to stop smoking, said method comprising:

(A) a non-conditioning educational program to educate the conscious mind to discourage smoking behavior;

(B) a hypnosis program to train the subconscious mind to discourage smoking behavior; and

(C) a substance selected from the group consisting of : a stop-smoking substance in an amount effective to aid in the reduction or cessation of a craving to smoke tobacco; a weight control substance in an amount effective to control body weight; and a dietary supplement substance in an amount effective to supplement the diet.

17. The method of claim 16, wherein said ~~stop-smoking~~ substance comprises a stop-smoking substance in an amount effective to aid in the reduction or cessation of a craving to smoke tobacco~~an anti-depressant~~.

18. The method of claim ~~17~~16, wherein said ~~anti-depressant~~substance comprises a weight control substance in an amount effective to control body weight~~a drug substance~~.

19. The method of claim ~~18~~17, wherein said ~~drug~~ stop-smoking substance comprises buproprion hydrochloride.

20. The method of claim ~~17~~16, wherein said ~~anti-depressant~~substance comprises a ~~nutritional~~dietary supplement substance in an amount effective to supplement the diet.

21. The method of claim ~~20~~16, wherein said ~~nutritional supplement~~substance comprises gotu kola.

22. The method of claim ~~20~~16, wherein said ~~nutritional supplement~~substance comprises kava kava.

23. The method of claim ~~20~~16, wherein said ~~nutritional supplement~~substance comprises lobelia.

24. The method of claim 16, wherein said ~~stop-smoking~~ substance comprises an anxiolytic.

25. The method of claim 24, wherein said anxiolytic ~~comprises~~ is a drug ~~substance~~.

26. The method of claim 24, wherein said anxiolytic ~~comprises~~ is a ~~nutritional~~dietary supplement.

27. The method of claim 16, wherein said ~~stop-smoking~~ substance ~~comprises~~ is a nicotine receptor antagonist.

28. The method of claim 27, wherein said nicotine receptor antagonist ~~comprises~~ is a drug ~~substance~~.

29. The method of claim 27, wherein said nicotine receptor antagonist ~~comprises~~ is a ~~nutritional~~dietary supplement.

30. The method of claim 29, wherein said ~~nutritional~~dietary supplement ~~comprises~~ is lobelia.

31. A stop smoking kit comprising:

(A) a non-conditioning educational program to educate the conscious mind to discourage smoking behavior;

(B) a hypnosis program to train the subconscious mind to discourage smoking behavior; and

(C) a substance selected from the group consisting of : a stop-smoking substance in an amount effective to aid in the reduction or cessation of a craving to smoke tobacco; a weight control substance in an amount effective to control body weight; and a dietary supplement substance in an amount effective to supplement the diet.

32. The method of claim 31, wherein said ~~stop-smoking~~ substance comprises a stop-smoking substance in an amount effective to aid in the reduction or cessation of a craving to smoke tobacco~~an anti-depressant~~.

33. The method of claim ~~32~~31, wherein said ~~anti-depressant~~substance comprises a weight control substance in an amount effective to control body weight~~a drug substance~~.

34. The method of claim ~~33~~32, wherein said ~~drug~~ stop-smoking substance comprises buproprion hydrochloride.

35. The method of claim ~~32~~31, wherein said ~~anti-depressant~~substance comprises a ~~nutritional~~dietary supplement in an amount effective to supplement the diet.

36. The method of claim ~~35~~31, wherein said ~~nutritional supplement~~substance comprises gotu kola.

37. The method of claim ~~35~~31, wherein said ~~nutritional supplement~~substance comprises kava kava.

38. The method of claim ~~35~~31, wherein said ~~nutritional supplement~~substance comprises lobelia.

39. The method of claim 31, wherein said ~~stop-smoking~~ substance comprises an anxiolytic.

40. The method of claim 39, wherein said anxiolytic ~~comprises~~ is a drug ~~substance~~.

41. The method of claim 39, wherein said anxiolytic ~~comprises~~ is a ~~nutritional~~dietary supplement.

42. The method of claim 31, wherein said stop-smoking substance ~~comprises~~ is a nicotine receptor antagonist.

43. The method of claim 42, wherein said nicotine receptor antagonist ~~comprises~~ is a drug ~~substance~~.

44. The method of claim 42, wherein said nicotine receptor antagonist ~~comprises~~ is a ~~nutritional~~dietary supplement.

45. The method of claim 44, wherein said ~~nutritional~~dietary supplement ~~comprises~~ is lobelia.

CLEAN COPIES OF CLAIMS

1. A method for helping a subject to stop smoking, said method comprising:

(A) providing a non-conditioning educational program to educate the conscious mind to discourage smoking behavior;

(B) providing a hypnosis program to train the subconscious mind to discourage smoking behavior; and

(C) providing a substance selected from the group consisting of : a stop-smoking substance in an amount effective to aid in the reduction or cessation of a craving to smoke tobacco; a weight control substance in an amount effective to control body weight; and a dietary supplement substance in an amount effective to supplement the diet.

2. The method of claim 1, wherein said substance comprises a stop-smoking substance in an amount effective to aid in the reduction or cessation of a craving to smoke tobacco.

3. The method of claim 1, wherein said substance comprises a weight control substance in an amount effective to control body weight.

4. The method of claim 2, wherein said stop-smoking substance comprises buproprion hydrochloride.

5. The method of claim 1, wherein said substance comprises a dietary supplement substance in an amount effective to supplement the diet.

6. The method of claim 1, wherein said substance comprises gotu kola.

7. The method of claim 1, wherein said substance comprises kava kava.

8. The method of claim 1, wherein said substance comprises lobelia.

9. The method of claim 1, wherein said substance comprises an anxiolytic.

10. The method of claim 9, wherein said anxiolytic is a drug.

11. The method of claim 9, wherein said anxiolytic is a dietary supplement.

12. The method of claim 1, wherein said substance is a nicotine receptor antagonist.

13. The method of claim 12, wherein said nicotine receptor antagonist is a drug.

14. The method of claim 12, wherein said nicotine receptor antagonist is a dietary supplement.

15. The method of claim 14, wherein said dietary supplement is lobelia.

16. A system for helping a subject to stop smoking, said method comprising:

(A) a non-conditioning educational program to educate the conscious mind to discourage smoking behavior;

(B) a hypnosis program to train the subconscious mind to discourage smoking behavior; and

(C) a substance selected from the group consisting of : a stop-smoking substance in an amount effective to aid in the reduction or cessation of a craving to smoke tobacco; a weight control substance in an amount effective to control body weight; and a dietary supplement substance in an amount effective to supplement the diet.

17. The method of claim 16, wherein said substance comprises a stop-smoking substance in an amount effective to aid in the reduction or cessation of a craving to smoke tobacco.

18. The method of claim 16, wherein said substance comprises a weight control substance in an amount effective to control body weight.

19. The method of claim 17, wherein said stop-smoking substance comprises buproprion hydrochloride.

20. The method of claim 16, wherein said substance comprises a dietary supplement substance in an amount effective to supplement the diet.

21. The method of claim 16, wherein said substance comprises gotu kola.

22. The method of claim 16, wherein said substance comprises kava kava.

23. The method of claim 16, wherein said substance comprises lobelia.

24. The method of claim 16, wherein said substance comprises an anxiolytic.

25. The method of claim 24, wherein said anxiolytic is a drug.

26. The method of claim 24, wherein said anxiolytic is a dietary supplement.

27. The method of claim 16, wherein said substance is a nicotine receptor antagonist.

28. The method of claim 27, wherein said nicotine receptor antagonist is a drug.

29. The method of claim 27, wherein said nicotine receptor antagonist is a dietary supplement.

30. The method of claim 29, wherein said dietary supplement is lobelia.

31. A stop smoking kit comprising:

(A) a non-conditioning educational program to educate the conscious mind to discourage smoking behavior;

(B) a hypnosis program to train the subconscious mind to discourage smoking behavior; and

(C) a substance selected from the group consisting of : a stop-smoking substance in an amount effective to aid in the reduction or cessation of a craving to smoke tobacco; a weight control substance in an amount effective to control body weight; and a dietary supplement substance in an amount effective to supplement the diet.

32. The method of claim 31, wherein said substance comprises a stop-smoking substance in an amount effective to aid in the reduction or cessation of a craving to smoke tobacco.

33. The method of claim 31, wherein said substance comprises a weight control substance in an amount effective to control body weight.

34. The method of claim 32, wherein said stop-smoking substance comprises buproprion hydrochloride.

35. The method of claim 31, wherein said substance comprises a dietary supplement in an amount effective to supplement the diet.

36. The method of claim 31, wherein said substance comprises gotu kola.

37. The method of claim 31, wherein said substance comprises kava kava.

38. The method of claim 31, wherein said substance comprises lobelia.

39. The method of claim 31, wherein said substance comprises an anxiolytic.

40. The method of claim 39, wherein said anxiolytic is a drug.

41. The method of claim 39, wherein said anxiolytic is a dietary supplement.

42. The method of claim 31, wherein said stop-smoking substance is a nicotine receptor antagonist.

43. The method of claim 42, wherein said nicotine receptor antagonist is a drug.

44. The method of claim 42, wherein said nicotine receptor antagonist is a dietary supplement.

45. The method of claim 44, wherein said dietary supplement is lobelia.

BEST AVAILABLE COPY

Directions: Take 1 tablet, 3 times/day, separate from meals, if you smoked 1 pac[illegible] day. If you smoked more, take 1 tablet, 4-6 times/day, separate from meals. Maximum 6 tablets/day as a dietary supplement.

- Keep out of reach of children.
- Store at 15-30°C (59-86°F).
- Protect from heat, light and moisture.
- Do not use if seal is broken.

WARNING: Pregnant or lactating women should consult with their physician prior to taking this product.

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

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STOP SMOKING SUPPLEMENT

dietary supplement / 90 tablets

Supplement Facts

Serving Size 3 Tablets — Servings per container 30

	Amount Per Serving	% DV
Niacin†	60 mg	300
Vitamin B6 (as pyridoxine HCl)	22 mg	1100
Folate (as folic acid)	225 mcg	56
Vitamin B12 (as cyanocobalamin)	75 mcg	1,250
DL-Phenylalanine	1125 mg	*
L-Tyrosine	337 mg	*
L-Glutamine	225 mg	*
5-HTP (from Griffonia simplicifolia seed)	22 mg	*
Stress Control Blend	100 mg	*
Wild jujube seed extract, chamomile flower extract, passion flower extract (aerial parts)		
SmokeStop Blend	337 mg	
Chinese Bupleurum root, Dang root, astragalus root, skullcap root, Korean ginseng root, dong quai root, peppermint leaf, lemon verbena (whole herb), Chinese herb, chamomile flower, ginger root, citrus peel, licorice root, and chicory root.		

* Daily Value (DV) not established

Other ingredients: dicalcium phosphate, microcrystalline cellulose, croscarmellose sodium, stearic acid, magnesium stearate, silica and pharmaceutical glaze.

† CAUTION: Transient flushing and feeling of warmth might be associated with the ingestion of Niacin containing products.

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EXCLUSIVE FORMULA DESIGNED TO:

- Promote Healthy, Steady Weight Loss
- Eliminate Impulse Eating and Snack Cravings
- Prevent Weight Gain for New Nonsmokers

Directions: Take one tablet with each meal, three times per day, as a dietary supplement.

- Keep out of reach of children.
- Store at 15-30°C (59-86°F).
- Protect from heat, light and moisture.
- Do not use if seal is broken.

WARNING: Pregnant or lactating women should consult with their physician prior to taking this product.

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ELIMINATE CRAVINGS

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WEIGHT CONTROL SUPPLEMENT

dietary supplement / 90 tablets

Supplement Facts

Serving Size 1 tablet

	Amount Per Serving	% DV
Chromium (as chromium dinicotinate glycinate)	100 mcg	83
Super CitriMax™ (as hydroxycitrate extract of Garcinia cambogia)	350 mg	*
Vanadium (as vanadyl sulfate)	50 mcg	*
Glucosol™ (1.0% colosolic Acid)	5 mg	*
Cal Aid [atractylodes (Atractylodes macrocephala)(rhizome), bitter orange (Citrus aurantium)(fruit)]	75 mg	
Herbal concentrates	150 mg	
Astragalus root, atractylodes rhizome, [illegible], Chinese red ginseng root, codonopsis root, licorice root, jujube date		

* Daily Value (DV) not established

Other ingredients: dicalcium phosphate, microcrystalline cellulose, croscarmellose sodium, stearic acid, magnesium stearate, silica and pharmaceutical glaze.

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

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STOP SMOKING

PRODUCING A DIFFERENCE

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Gorayeb Seminars, Inc. Mission Statement

To provide information, education and training that enables people to improve their health and the quality of their lives.

Welcome to Gorayeb Seminar's Stop Smoking with Hypnosis program. . You deserve congratulations on making the decision to finally become a non-smoker and for choosing to attend our Stop Smoking Seminar. Listed below are just a few of the many ways smoking has cost you over the years. Take a moment to fill out the Dollar Cost Worksheet and to read the Health Cost Information Section. We think you will find both of these sections interesting and motivating.

The Dollar Cost Of Smoking

How Much Money Has Smoking Cost Me?

A) Number of cigarette packs you smoke per day---------- _____
B) How much you pay for each pack---------- $ _____
C) Multiply A times B = Cost per Day---------- $ _____
D) Multiply C by 365 days----------x 365
E) Equals the amount you spend per year ----------$ _____
F) Number of years you have smoked ----------x _____
G) Multiply E times F. Equals Your Smoking Cost To Date ------- $ _____

How Much Can I Save?

H) From Line E, enter amount you spend per year-- ----------$_____
J) Multiply H times 10. Equals the amount of money you will save in the next ten years if you quit now----------$_____

The Health Costs Of Smoking

Major Poisons In Cigarettes: (Just 19 of the more than 3,000 poisons you inhale when you smoke. 1989 Surgeon General report)

Carbon monoxide	Toxic (EPA Controlled Substance. Same as car exhaust.)
Carbonyl sulfide	Toxic (EPA Controlled Substance)
Benzene	Toxic & Carcinogenic (EPA Regulated. Causes brain death)
Formaldehyde	Carcinogenic (Used for embalming dead bodies)
3-Vinylpyridinen	Suspected carcinogen
Hydrogen cyanide	Toxic (Regulated Pesticide. Standard rat & animal poison)
Hydrazine	Carcinogenic (OSHA Banned. Used as auto racing fuel)
Nitrogen oxides	Toxic (EPA regulated Auto Emission)
N-Nitrosodimethylamine	Carcinogenic
N-Nitrosopyrrolidine	Carcinogenic
Tar	Strong carcinogen (Clogs lung tissue)
Nicotine	Toxic (EPA Registered Pesticide)
Phenol	Causes both cancerous and benign Tumors
Catechol	Acts as Catalyst for other carcinogens
o-Toluidine	Carcinogen (Banned in all consumer products in 1983)
N-Nitrosodiethanolamine	Carcinogenic
Cadmium	Carcinogenic
Nickel	Toxic pesticide & carcinogen (EPA Reg. Used for deforestation)
Polonium 210	Extremely Radioactive Carcinogen (Causes 135,000 deaths / year)

What These Poisons Have Done:

- Nicotine changes your metabolism causing blood sugar, insulin and adrenaline highs that stress your system.
- Each puff creates 130,000 "Free Radicals" that damage body cells, cause early aging and low energy levels.
- Nicotine replaces the neurotransmitters in your brain causing a drug addiction rated as strong as Heroin.
- Second hand smoke endangers your family. The third leading cause of preventable deaths in America.
- Smoking depletes the skin's natural collagens causing facial wrinkles, roughness and premature aging.
- Cigarettes contain high levels of radioactive Polonium 210. The MAJOR cause of smoking induced cancers.
- 425,000 AMERICANS DIE EACH YEAR FROM DISEASES CAUSED BY SMOKING!
- Smokers who quit by age 50 cut their risk of dying in half for their next 16.5 years.
- 2 times as many smokers die from heart disease as do nonsmokers.
- Smokers are 17 times more likely to die from lung cancer than nonsmokers.

CHANGES IN YOUR BODY WHEN YOU STOP SMOKING

Within 20 minutes of last cigarette

Blood Pressure drops to normal
Pulse rate drops to normal rate
Body temperature of hands, feet increases to normal

8 Hours

Carbon monoxide level in blood drops to normal
Oxygen level in blood increases to normal

24 Hours

Chance of heart attack decreases

48 Hours

Nerve endings start regrowing
Ability to smell and to taste things is enhanced

72 Hours

Bronchial tubes relax, making breathing easier
Lung capacity increases

2 Weeks to 3 Months

Circulation improves; Walking becomes easier
Lung function increases up to 30 percent

1 to 9 Months

Coughing, sinus congestion, fatigue, and shortness of breath decreases
Cilia regrows in lungs, increasing ability to handle mucus, clean the lungs, reduce infection
Body's overall energy level increases

5 Years

Lung cancer death rate for average smoker (one pack a day) decreases from 137 per 100,000 people to 72 per 100,000

10 Years

Lung cancer death rate for average smoker drops to 12 deaths per 100,000 -- almost the rate of non-smokers.
Precancerous cells are replaced. Other cancers -- such as those of the mouth, larynx esophagus, bladder, kidney and pancreas -- decrease.
(There are 30 chemicals in tobacco smoke that cause cancer.)

ALL BENEFITS ARE LOST WHEN YOU SMOKE JUST 1 CIGARETTE A DAY.

Do You Have To Gain Weight When You Quit Smoking?

The average person who quits smoking gains between 20-60 pounds within the first 6 months after quitting. There are three main reasons for this weight gain and each can be prevented:

1) The body works harder to stay alive when you smoke. The carbon monoxide in cigarettes displaces oxygen in the blood so the heart has to work harder and faster to get the needed oxygen to the body's cells. The metabolic rate speeds up to remove all the toxins inhaled while smoking. On average, the metabolic rate slows by 400 calories per day after quitting. If eating habits remain the same, this equates to a pound gained every 9 days. People quitting smoking should consider extra exercise, reducing food intake and taking supplements that block the conversion of carbohydrates into sugars and stored fat.

2) Since smoking causes large insulin releases, the body becomes highly insulin resistant. (Hyper-insulinemia). Because of this insensitivity, (which usually last 90-120 days after quitting), 2-3 times the amount of insulin is needed to process the food ex-smokers eat. Insulin is the primary fat storage hormone. So most of the food consumed is converted into stored body fat and not used for energy. Recent ex-smokers should limit intake of all sweets, carbohydrates and sugars as much as possible and consider taking specific supplements designed to restore the body's normal sensitivity to insulin.

3) Sweets and carbohydrates cause the brain to release the same neurotransmitters, such as Dopamine, as does Nicotine. Because these foods are used to satisfy the body's need for nicotine, most ex-smokers have nearly irresistible cravings for sweets and carbohydrates which then cause weight gain. Ex-smokers should consider substituting exercise for these cravings. It is also considered beneficial to use Dopamine producing supplements to help reduce or eliminate food cravings.

How and Why Cigarettes Are Very Addictive

(THE PHYSIOLOGICAL PROGRESSION OF SMOKING)

Stage 1

Light a cigarette and inhale. This takes about 7 seconds. During this inhalation, nicotine enters the bloodstream through the nasal membranes and rushes directly to the brain. This is a faster transfer method than direct intravenous injection. Once in the brain, nicotine causes large releases of Dopamine and Serotonin neurotransmitters. These neurotransmitters cause that "relaxed and powerful" feeling. But soon the brain cells become resistant to these neurotransmitters. The brain then requires ever more nicotine to create the same effect. Smoking becomes addictive and self-perpetuating.

Stage 2

Seven seconds to fifteen minutes later, nicotine also enters the liver, which in turn releases sugar into the blood stream. This results in a physical uplift, not from the cigarette, but from the release of sugar into the blood stream. Combined with the high neurotransmitter levels, you feel confident and full of energy.

Stage 3

Due to the high sugar content in the blood, the pancreas will release insulin into the blood stream and blood sugar levels will drop lower than when you started to smoke. At the same time, neurotransmitter release also stops. This combination makes you feel fatigued, irritable, hungry and craving another cigarette. This same cycle occurs when you eat candy bars. This is why you must avoid sweets the first week after tonight. Sweets can trigger the desire to smoke.

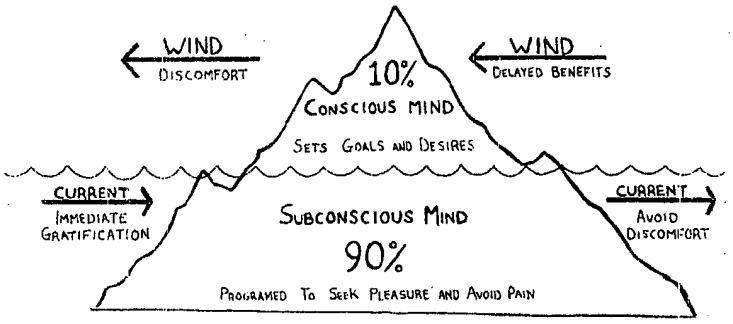
Stage 4

Fifteen to twenty minutes after beginning to smoke, the nicotine stimulates the nervous system and causes the release of adrenaline into the body, producing increased heart rate and respiration along with feelings of tension. This tension begins just when blood sugar and neurotransmitter levels are "crashing".

Stage 5

Because of the tense feelings of Stage 4, and because of the lower blood sugar and neurotransmitter levels, you begin to desire another cigarette, which has the false illusion of helping you to relax, and thus the smoking cycle begins again.

The addictive effects of smoking and nicotine appears very depressing when the true reality of it is presented as it is in the above section. But it is also a reality that this progression is physically rewarding and pleasurable while it is happening (See the following page to understand why). Because of the physical pleasures, most people find it difficult to overcome the immediate pleasures despite the well-known health risks involved in smoking. Studies have shown that most of the decisions we make are made by the subconscious mind. Since birth, our subconscious minds have been programed to seek pleasure and avoid pain. This lifelong programming makes it very difficult for most people to delay an immediate gratification in favor of future health benefits.



The only way to get the "iceberg" to follow the proper path is to reprogram the subconscious "current" so that it flows in the same direction as the conscious "wind".

The Biology Of Nicotine Addiction

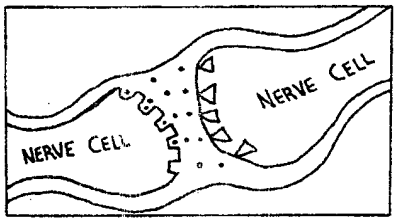
Nicotine is a very addictive drug that works on the mind (the psychological part of us) and on the brain itself (the physical part). Hypnosis is extremely effective dealing with the psychological addiction nicotine causes. Using hypnosis, the subconscious mind is reprogrammed to find smoking unpleasant.

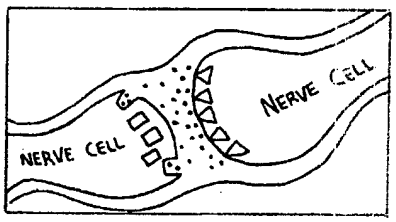
The physical brain is composed of millions of cells called neurons. In some ways, neurons act like computers. They receive and process messages and then send new messages to other neurons. The messages are transmitted using chemicals called neurotransmitters. Depending on the neurotransmitter used, (more than 50 are known so far), the receiving neuron "understands" a certain type of message.

One of the most potent neurotransmitters is called Dopamine. The neurochemical message Dopamine produces is one of "feeling good", confidence, relaxation and a general sense of heightened well being. Cocaine, Heroin *and NICOTINE* stimulate the release of Dopamine. This Dopamine release causes all the relaxing, pleasurable effects of smoking. However, it is a false, drug-induced sense of relaxation and the body adjusts to the high Dopamine levels in about 90 days.

After about 90 days, the brain's nerve cells becomes less sensitive to Dopamine. To prevent damage from the high Dopamine levels each nerve cell **reduces the number of dopamine receptor areas it has.** Fewer dopamine receptor areas means that higher Dopamine levels are required (more nicotine) to get the same pleasurable feelings from smoking. You smoke more and more just to get the same feelings.

Normal Condition→ Dopamine receptors and emitters matched.

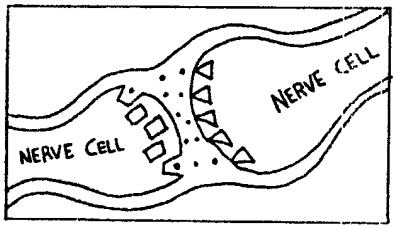




← **Over stimulation** Nerves close receptors to protect themseleves

Once you stop smoking, Dopamine levels drop very quickly. Usually within 5-7 days. **But the brain's neurons need 90 days or more to rebuild the Dopamine receptor areas they eliminated** when the nicotine was over stimulating Dopamine production. Therefore, you not only lose the sense of well being, relaxation and calm you experienced while smoking, you actually become irritable, short tempered and lose concentration. Most importantly, your brain stimulates your body to get more nicotine so it can feel better again! You experience strong smoking urges.

LEGEND
△ Emitter
□ Closed Receptor
⊔ Open Receptor
• Dopamine



← **Withdrawal** Dopamine production drops, but receptors are still closed

These urges combine with reduced brain functions to make you experience the dreaded withdrawal symptoms. Often accompanying the urge to smoke is an impulse to overeat. Sweets and sugars also stimulate Dopamine production and can sometimes function as "nicotine substitutes". But they also cause weight increase (aver. 8-10 lbs. a month) and physical problems of their own.

These symptoms are exclusively chemical in nature and reside in the physical part of the brain. The good news is that since they are chemically induced, they will gradually disappear as the neurons rebuild their Dopamine receptors. After about 90 days, this rebuilding process is complete. The brain is again sensitive to Dopamine and functions as it did before you started smoking. Smoking urges decrease in frequency and intensity. It becomes much easier to remain a non-smoker.

It is important to note that EVEN ONE CIGARETTE WILL HALT THIS RECOVERY PROCESS COMPLETELY. It will take several more weeks after that one cigarette for the neurons to again start rebuilding their Dopamine receptor areas. During this time, the withdrawal symptoms will reoccur.

It is very important to resist the smoking urges that occur in the first 90 days. This will make complete recovery possible in the shortest amount of time with the least withdrawal symptoms. Use the techniques and the nutritional information contained in this seminar to insure successfully becoming a non-smoker. They are designed to make the process of becoming a non-smoker comfortable and easy.

USING FOOD AS AN AID TO STOP SMOKING

SUGGESTIONS (Do this as often as possible)

* Eat 3 meals a day, including breakfast
* Have protein and complex carbohydrates (whole grains, fresh vegatables) with each meal
* Limit sugar intake. Avoid simple carbohydrates like rice and wheat.
* Drink 8 glasses of non-caloric liquids a day - water with lemon, water, seltzer, herbal tea, etc. Keep a pitcher of water on your desk. You'll easily drink 8 glasses a day.
* Between meals, drink water or eat a piece of fruit
* Eat plenty of protein - lean meat, fish, poultry, low fat cheese
* Increase your mineral intake, especially calcium/magnesium and chromium/vanadium
* Take a vitamin supplement with a high antioxidant content to eliminate "Free Radicals".
* Take a B complex supplement, preferably one that contains Biotin, and Vitamin C
* Add Niacin-bound Chromium (Dinicotinate, Glycinate or Chelate) to your diet
* Eats lots of fruits, vegetables and salads
* As soon as you finish eating, leave the table and go brush your teeth
* When possible, use a mouthwash

... A Few More Suggestions

* Do not skip any meals, never miss breakfast
* Limit sugar and simple carbohydrate intake - read packaging labels
* Minimize beverages with caffeine - tea, colas, coffee, chocolate
* Reduce alcohol

WHY THIS ATTENTION TO FOOD, WHY THESE RECOMMENDATIONS

If your blood sugar level gets low, you will crave a cigarette or something sweet, either of which will boost your sugar level for 10 to 20 minutes and then cause a crash, triggering another urge for a cigarette or a sweet. By eating 3 meals a day, you will tend to have a stable blood sugar level, and this will minimizes any cigarette or eating urges. Protein with complex carbohydrates at breakfast allows stable sugar levels all through the day.

Avoiding sugar/sweets eliminates the blood sugar surge/crash cycle and reduces cigarette craving. Drinking 8 glasses of non-caffeine liquid helps your body clear out the nicotine, helps you feel full all day, so you don't overeat or snack, and MOST IMPORTANTLY, acts as a replacement for smoking. Fruit and fruit juices help maintain blood sugar levels. Caffeine promotes irritability, and alcohol, in addition to associations with smoking, has a very high sugar content and can make you forget how important being a non-smoker is to you.

Increase your mineral intake the first 90 days. Your body will be losing minerals when you quit smoking. Calcium has a calming and relaxing effect on your body and will minimize any tendency toward irritability. Chromium regulates your body's insulin production and helps prevent low sugar "crashes" that trigger the smoking urge. B vitamins help to minimize the effects of stress and reduce mood changes. Antioxidants are necessary to repair the damage to your body that years of smoking has caused.

IF ANY OF THESE SUGGESTIONS CONFLICT WITH INSTRUCTIONS FROM YOUR PHYSICIAN, HAVE YOUR PHYSICIAN ADVISE YOU.

HANDLING URGES

If you ever get a desire or craving for a cigarette:

* Stop what you are doing
* Take 3 deep breaths to eliminate the desire to smoke
* Physically get up and move, even if it's just to stand up
* Do a stretch or two
* Take another 3 deep breaths, and another 3 if necessary
* Drink water, preferably with lemon
* Get a breath of fresh air
* Awareness technique - Look around the room and say, "Now I am aware of the chair, now I am aware of the lamp," --- continue making "Now" statements until the urge passes.

Something to know about urges and desires:

1. You don't have to fulfill them
2. If you do nothing, they will just go away and recur less frequently
3. Smoking doesn't end an urge, it just placates it and generates another urge in 15 to 30 minutes

An additional technique that you may want to experiment with: time the duration of the urges. You'll need a watch which indicates seconds. The way to proceed is as follows: If and when you get an urge, look at your watch and write down the exact time to the second it began. Then use the recommendations on the top of this page. When the urge has passed, note the time and calculate how long the urge lasted. "MAKE A GAME OUT OF THIS". Set a one-month goal to be able to get rid of any smoking urge within 30 seconds. This will give you perspective on what is really happening and help you disassociate from the urge.

CHANGING YOUR ENVIRONMENT

Certain environments or situations trigger emotional desires and biological urges. For example, when going to the movies - many people who rarely eat popcorn, will order popcorn. We associate eating popcorn and watching movies.

Change your routines to minimize the triggering of smoking desires and urges:

* If you normally smoke a cigarette first thing in the morning, change the sequence of your morning routine. Brush your teeth, take a shower, go into the kitchen and drink some juice.
* At work, hold the phone in your other hand, or stand instead of sitting while on the phone.
* Instead of a coffee break, take a juice break or go for a walk.
* Make a list of people, places, activities that you do not associate with smoking. Plan to spend some time engaged with them this month.
* Rearrange your desk/office.
* Sit in a different place at dinner.
* Change your schedule for making calls, opening mail.

P.S. Don't get too H.A.L.T. - Hungry, Angry, Lonely or Tired. They are triggers for smoking. Change your environment, call someone, or have a salad, fruit or glass of water.

IMPORTANT THINGS TO DO

1) **Practice the mental training technique** on page 8 (or play the reinforcement tape) at least once a day for the next 28 days and 3-4 times a week after that until you are comfortable as a non-smoker.
2) **Within the next 3 hours** after this class, throw out all your cigarettes and related items such as lighters, cases, ashtrays, etc. Having these items around reminds you of the desire to smoke. Empty all ashtrays in your cars also.
3) **Take 3 Deep Breaths** to stop any immediate desire to smoke - or to simply relax. If necessary, take another 3 deep breaths and another 3. Use this technique and it will work for you.

REMEMBER – THERE IS NO SUCH THING AS AN OCCASIONAL CIGARETTE!

MENTAL TRAINING EXERCISE

Find a quiet place where you will not be disturbed. Wear loose clothing or loosen tight clothing. Sit in a comfortable position with your eyes closed.

Take a few slow, deep breaths and begin to relax yourself.

Relax your entire body, starting with your head and going toward your toes. Imagine a beautiful white cloud gently massaging your scalp. Mentally say to yourself: "soothing and relaxing."

Then imagine the beautiful white cloud gently messaging your forehead. Mentally repeat to yourself: "soothing and relaxing."

Continue to do this with your eyelids, cheeks, throat, neck, shoulders, chest, abdomen, thighs, knees, calves, feet. Mention with each new part: "soothing and relaxing."

Next, **relax your mind**. Do this by imagining in as vivid detail as possible, passive, relaxing scenes, i.e.,

A walk in the country on a beautiful, warm, spring day. Imagine the spring flowers in bloom, notice their color and texture. Imagine a gentle breeze blowing and the wonderful fragrances in the air. Imagine the sounds in the country as you enjoy your walk - the wind rustling through the trees, perhaps some birds chirping. Imagine enjoying your walk and feeling relaxed.

While you are relaxing your body and mind, occasionally take slow, deep breaths.

Imagine a cigarette of the brand you used to smoke. As you mentally picture it say to yourself: "seven minutes of life gone - what a waste," then mark a big red NO over the cigarette and mentally say "no desire."

Next, recall the bad, distasteful feeling you had during the hypnosis when you imagined chewing on a cigarette. Bring back the harsh bitter feelings and mentally say "no desire."

Next, visualize four different scenes that clearly let you know that you have succeeded easily at being a non-smoker. Include in the scenes positive feelings about your accomplishment, conversations (if appropriate), and how you might talk to yourself.

Occasionally **repeat the following phrases**:

" I am a permanent, lifelong non-smoker."

" Taking 3 slow deep breaths will eliminate the immediate desire to smoke."

" It is easy for me to be a non-smoker."

" All desire to smoke is gone from my body and mind forever."

" I am proud of myself for being a non-smoker. I feel great about being a non-smoker."

When you are ready to come out of the relaxation exercise, give yourself positive instruction, i.e.,

"When I open my eyes, I will be relaxed, in a good mood, and refreshed."

"When I open my eyes, I will be energized and ready to ...."

Success Guarantee

You are entitled to repeat this seminar as often as you like - Free of any charge.

SAVE THIS WORKBOOK, and present it at any Gorayeb Stop Smoking Seminar Nationwide for free admission.

This workbook is non-transferable and valid only for the person named above.

Proof of I.D. is required when repeating

Gorayeb Seminar Reinforcement Tapes

This seminar is designed so you can absolutely stop smoking right now. The techniques you learn tonight and the special hypnotherapy you experience will combine to make this happen. But quitting smoking is probably the greatest physical and psychological challenge most people will ever face. The nutritional products detailed in this book are designed to minimize the physical addiction problems associated with quitting. The tapes listed below will help reinforce the psychological techniques and strengthen your stop smoking program. When combined with this seminar, there is no stronger, more effective way to quit!

Stop Smoking Hypnosis Reinforcement Tape

This special tape is designed to reinforce the motivation and stop smoking techniques you learned in tonight's seminar. Available whenever you need to strengthen your stop smoking program, just play it and regain your program's momentum. The tape uses powerful hypnosis techniques to reinforce your desire to quit smoking while strengthening your will to do so.

Stop Smoking Subliminal Tape

This very special tape has soothing music on both sides. **But**, inside the music are imbedded subliminal messages. These messages, that your subconscious will hear but you will not consciously notice, reinforce your desire to become a non-smoker while helping you gain the confidence and desire to succeed. This tape may be played while driving, allowing you to resist one of the most tempting smoking occasions.

The positive, subliminal messages on this tape combine with the hypnosis review on the Stop Smoking Reinforcement Tape to make the strongest stop smoking reinforcement program available.

Freedom From Stress Tape

A special program tape just for people who quit smoking. Side One contains powerful hypnotic techniques that reduce stress levels and allow you to react normally to various stimuli as your body and mind readjusts themselves. Many new non-smokers return to smoking due to stress situations. Using the powerful hypnosis techniques on this tape, you will be more able to resist the temptation to smoke in response to stressful situations.

Side Two contains subliminal stress relief messages hidden inside special music. Just like the Stop Smoking tape, this allows the tape to be played in the car, one of the today's most stressful occasions possible. Where ever you are, whenever the smoking urge strikes as a response to stress, just listen to this tape. You will be better able to overcome the stressful situation while resisting the urge to smoke.

Hypnosis Weight Loss Reinforcement Tapes

One of the most feared side effects experienced by the new non-smoker is weight gain. The new non-smoker's metabolism slows down as their system loses the nicotine drug. Plus the urge to eat sweet or fatting foods increases as their body adjusts to working without the drug. These factors combine to cause weight gain.

The Hypnosis Weight Loss Reinforcement Tape employs special hypnotic techniques designed to help you conquer this special problem you will encounter as you quit smoking. Use this tape on a regular basis or whenever those cravings for sweets occur. It is even more effective when used as part of an integrated, nutritional program employing ISOTRIM-CX.

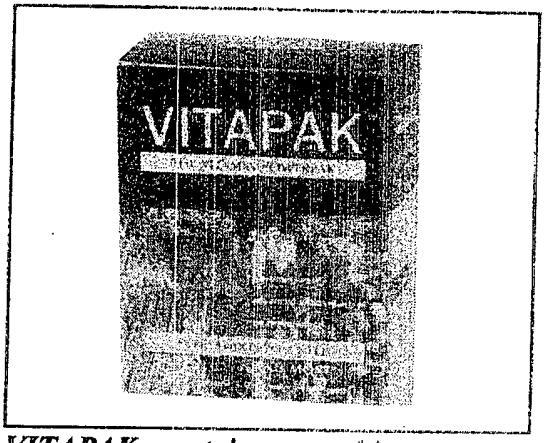
Personal Hypnosis Library

The complete collection of the most popular and useful support tapes available. A special, Double Induction Weight Loss tape that uses multiple track recording techniques is included. Also included in the Personal Hypnosis Library are hypnotic tapes to relieve pain, increase memory power, enhance sexual performance for men and women, increase self confidence, and get a good night's sleep. Ten powerful hypnotic tapes, twelve subjects, in one economical package.

VITAPAK

The Vitamin Power Pack

An Exclusive, Comprehensive Blend of 49 vitamins, minerals, antioxidants, photonutrients and herbs in an exclusive, patented *TIME-RELEASE* formula designed to provide nutrients to help your body rebuild and repair itself. VITAPAK also contains Probiotics, which are ideal for the digestive system.



VITAPAK contains everything your body needs and more!

NOW In An Exclusive Time Release Formula

VITAPAK's key vitamins and antioxidants are released as your body needs them over an 8 hour period. This patented nutrient delivery system uses natural fibers to mimic Mother Nature's own whole foods. It provides prolonged nourishment and protection rather than one burst. No other nationally advertised vitamin and antioxidant supplement does this.

VITAPAK is designed to:

- Provide high amounts of antioxidants to help your body scavange the dangerous "Free Radicals" created in your body by smoking. Free Radicals damage body tissue and cells, breakdown the body's collagen and elastin causing higher blood pressure, wrinkles and premature aging.
- Provide nutrients to help your body reduce homocysteine levels, a major culprit in heart disease.
- Suppy nutrients to help your body increase insulin effectiveness and promote healthy blood sugar levels.
- Provide every essential mineral and trace mineral your body needs.
- Supply advanced phytonutrients to help strengthen your immune system.
- Provide high Probiotic levels to provide nutritional support for a healthy digestive system.
- Provide the most complete and balanced multivitamin blend available critical to the optimal functioning of 860 enzymes in the body..

Each box contains 30 packets of 4 tablets per packet. (30 day supply). Each Daily Packet contains:

Multi-Vitamin Support		**%MDA**
Vitamin A	5000IU	100
Vitamin C	180mg	300
Vitamin D	400IU	100
Vitamin E	100IU	333
Vitamin K	80mcg	100
Thiamin	7.5mg	500
Riboflavin	8.5mg	500
Niacin	100mg	500
Vitamin B6	25mg	1250
Folic Acid	600mcg	150
Vitamin B12	60mcg	1000
Biotin	300mcg	100
Pantothenic Acid	50mg	500
Choline	25mg	**
Inositol	25mg	**
PABA	25mg	**

** Daily Value Not Established

Multi-Mineral Support		**%MDA**
Calcium	383mg	38
Iron	9mg	50
Magnesium	150mg	38
Zinc	15mg	100
Copper	2mg	100
Manganese	2mg	100
Phosphorus	37mg	4
Molybdenum	25mcg	33
Boron	1mg	**
Silicon	5mg	**

Carbohydrate Metabolism Support		
Selenium	125mcg	179
Chromium	100mcg	83
Vanadium	50mcg	**

Collagen Support Compounds		
Biotin	300 mcg	100
Grape Seed Extract	25 mg	**
Bilberry Extract	10 mg	**

Advanced Antioxidants	
N-Acetylcysteine	50mg
Green Tea Leaf Extract	100mg
Quercetin	50mg
Polygonum Cuspidatum	10mg
Grape Seed Extract	25mg
Isoflavones	10mg
Tumeric Rhizome	40mg
Phenalgin	50mg
Cruciferous Veg. Conc.	50mg
Bilberry Extract	10mg
RoseOx-Triple Antioxidant	25mg

Energy Enhancing Herbal Blend

Panax Ginseng Root;
Red Jujube Date
L-Glutamine 265 mg

Probiotic Blend

L-acidophilus; L. Plantarum; Bifidobacterium Bifidum; L. Casei 2.5 billion CFU

Everything you need ... When you need it!

You can reach VITAPAK Nutritional Products toll free at 1-800-836-3663

FREE SAMPLE
INTRODUCTORY OFFER
VITAPAK - *THE Vitamin Power Pak*

Your body will be using large amounts of vitamins and nutrients as you stop smoking. Your body will also be using large amounts of calcium and magnesium that must be replaced. Plus, it will need extra nutrients as it reconstructs damaged nerve endings and lung tissue. Your entire body will be rebuilding a healthier you. **It will need to replace these vast amounts of nutrients and vitamins without the stress and mood changes that could damage your stop smoking program.**

VITAPAK has all the vitamins and nutritional supplements you will need

- In one easy to use package -

The VITAPAK program is designed to work alone, or with NICAZAN, to help your stop smoking program succeed. Once a month, 1 box (a 30 day supply) is shipped to you automatically. This way, VITAPAK will always be available to sustain your body as it rebuilds a healthier, new you. This subscription program also offers **HUGE SAVINGS** over the regular price.

***SAVE more than 50%* off the regular $49.95 per box price.**

The special program price is just $24.95 per box*

Try one box **FREE****. You can cancel at anytime without cost or obligation with just a free 800 phone call. But it may be impossible to duplicate VITAPAK's nutritional content and stop smoking support at this discount program's low cost. Enroll in the program *NOW*!

PLEASE TEAR HERE

YES! SEND ME THE FREE VITAPAK BOX:

DATE: _____

NAME: _____ AGE: _____

HOME ADDRESS: _____ E-Mail: _____

CITY: _____ STATE: _____ ZIP: _____

BUSINESS PHONE: (___) _____ EXT: _____ HOME PHONE : (___) _____

Type of Credit Card: Visa _____ Mastercard _____ Amex _____ Discover _____

Card Number: _____ Exp. Date: _____

Signature: _____ *(Required)*

- ☐ Credit Card on File - check only if you paid tonight's admission by credit card
- ☐ Check on File - Debit My Account- Check only if you paid tonight's admission by check.
- ☐ Voided Check Attached - Debit My Account

I understand that I may cancel the VITAPAK subscription program at any time by calling 1-800-836-3663

* There is an additional $3.95 Shipping & Handling charge each shipment.
** There is a onetime $ 4.95 shipping and handling fee on this free shipment.

Notes

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HYPNOSIS STOP SMOKING REINFORCEMENT AIDES

Stop Smoking Double Induction..... $25.00
Stop Smoking Subliminal $25.00
Weight Loss Double Induction $25.00
Relief From Stress and Cravings.....$25.00

STOP SMOKING POWER PACK

Stop Smoking Double Induction.....Weight Loss..... ..... $75.00
Stop Smoking Subliminal.....Relief From Stress and Cravings

STOP SMOKING REINFORCEMENT NUTRITIONAL AIDS

NICAZAN (30-day supply) .....$40.00 Each.....3 Bottles (90 day supply) $80.00
ISOTRIM-CX (30-day supply).....$40.00 Each.....3 Bottles (90 day supply) $80.00
RESPIRCLEAR (30 day supply)...$30.00 Each.....3Bottles (90 day supply) $60.00

90 DAY COMPLETE THERAPY SUPPORT PACKAGE:

ALL FOUR STOP SMOKING POWER PACK TAPES
3 Bottles NICAZAN.....3 Bottles ISOTRIM-CX.....3 Bottles RESPIRCLEAR
$275.00

60 DAY COMPLETE THERAPY SUPPORT PACKAGE:

ALL FOUR STOP SMOKING POWER PACK TAPES
2 Bottles NICAZAN.....2 Bottles ISOTRIM-CX.....2 Bottles RESPIRCLEAR
$225.00

30 DAY COMPLETE THERAPY SUPPORT PACKAGE:

ALL FOUR STOP SMOKING POWER PACK TAPES
1 Bottle NICAZAN.....1 Bottle ISOTRIM-CX.....1 Bottle RESPIRCLEAR
$155.00

Personal Hypnosis Library

Lose Weight Double Induction
Freedom from Insomnia
Creating Wealth & Prosperity
Increased Productivity
Super Relaxation
Increase Self-Confidence
Sexual Enhancement
Release Pain/Arthritic Pain
Memory & Concentration
Freedom from Stress
Eliminate Headaches & Migraines

$89.99

APPENDIX

Neurotransmitters -- These compounds transmit information within the nervous system. The brain contains billions of nerve cells. To create thoughts, memories, emotions and feelings, each nerve cell has to communicate with millions of the brain's other nerve cells. This communication is facilitated by compounds called neurotransmitters. About 50 such compounds have been identified so far. Each neurotransmitter has a specific role. For example, certain experiences cause the brain to release dopamine or serotonin. In appropriate amounts this is natural and healthy. But when addictive drugs like nicotine are used, they may over stimulate the release of certain neurotransmitters and throw the system out of balance. The brain can habituate to these new levels and require even greater stimulation and thus the addictive cycle has begun.

5-HTP -- 5-Hydroxy-Tryptophane (5-HTP's full name) is an important amino acid, (amino acids are the building blocks that make up all our bodies proteins), that the body uses to produce the neurotransmitter Serotonin. Serotonin produces feelings of strength, well being and influences mood. Proper serotonin levels also relieves depressed feelings and may help relieve nicotine withdrawal symptoms. Most prescription drugs designed to control depression work by artificially increasing Serotonin levels. 5-HTP works naturally instead, allowing the body to produce Serotonin just as it needs it to feel better. 5-HTP is a precursor to Serotonin which is a precursor to Melatonin. Melatonin helps promote sleep and relaxation.

Chromium Dinicotinate Glycinate -- Chromium is one of the essential trace minerals that your body requires to function; it supports stable blood sugar levels. Chromium Dinicotinate Glycinate helps prevent sugar and sweets cravings (reducing the urge to smoke in ex-smokers, see page 4 for more details) while lowering LDL, and increasing HDL, cholesterol levels. It is a master nutrient that is essential for converting food into energy or stored body fat. Research at several major universities have shown that a biological form of chromium (chromium dinicotinate glycinate) increases the cell's sensitivity to insulin which increases the body's ability to convert food into energy, reduce fat formation, convert protein into muscle. Without sufficient chromium, insulin becomes very inefficient and the body is forced to produce much more insulin to process the food that is consumed. Since two of insulin's functions are to convert food into stored body fat and to protect stored fat from being burned, this extra insulin results in increased body fat. This promotes weight gain and lower felt energy levels. Extra insulin also creates wide swings in blood sugar levels that can result in cravings for sweets and carbohydrates as well as frequent "mood" swings. Up to 85% of Americans are chromium deficient. Chromium Dinicotinate Glycinate (bound with Niacin) is one of the most efficient form of chromium as it is "ready to use" unlike chromium picolinate and other forms.

DL-Phenylalanine -- (DLPA) An amino acid that is utilized by the body for numerous functions including synthesis into Dopamine. The brain uses Dopamine (nicotine forces the creation of mega-doses of dopamine with each puff) to convey feelings of well being and control. Drug addiction research has found this amino acid to be an effective treatment for relieving the physical cravings caused by addictive drugs like nicotine. The studies concluded that DL-Phenylalanine *allows* the body to synthesize dopamine without nicotine being present. This helps relieve withdrawal symptoms naturally, allowing gradual recovery. DLPA has been shown to help maintain natural body chemicals known as encephlins, which are the brains own analgesic (pain killer). This helps to relieve withdrawal.

Folate -- Folate is a member of the B complex family of vitamins. When combined with Vitamins B-6 and B-12, published research has shown it to relieve feelings of depression and anxiety. Folate is deficient in the American diet. Average intake is about 56% of the recommended daily amount (RDA) (227mcg intake vs 400mcg RDA). Other studies have shown it critical to protect DNA and to dramatically lower the levels of a harmful body chemical known as homocystine. High levels of homocysteine can increase the risk of heart attack.

Gar-Aid -- In combination with **Super CitriMax**, these natural herbs have been found to help reduce carbohydrate cravings. Fewer simple carbohydrates eaten causes less fluctuations in blood sugar which may minimize cravings due to low blood sugar.

Ginseng -- For hundreds of years, Asian herbalists have testified to Ginseng's positive effects on longevity and its ability to increase the entire body energy levels. Some studies indicate ginseng to regulate and normalize blood pressure and blood sugar levels. It has been known as the "King of Herbs" and cure-all and has also demonstrated an ability as a mild sexual enhancer.

APPENDIX

Glucosol -- The Asian herb Banaba contains a compound called corosolic acid which is used in Asia to control high blood sugar. Glucosol's unique blood sugar control abilities reduce the body's daily insulin needs while keeping blood sugar levels stable and under control. Stable blood sugar levels are important to eliminate smoking and eating cravings. The reduced need for insulin in the presence of Glucosol also results in more food being converted into useful energy and less into stored body fat.

Green tea extract – Tea is the second highest consumed beverage in the world (behind water). There are literally thousands of research papers discussing the antioxidant protective benefits of green tea. One of its major constituents is Epigallocatechin gallate (EGCG). Recent studies in both the US and Europe show that green tea standardized to EGCG helps to increase calorie burning.

Gymnema Sylvestre -- This all-natural herb helps control the bloods sugar level which can result in reduced insulin production. Due to it's nontoxic nature and sweetness-suppression activity, *Gymnema sylvestre* can play a role in a sound weight reduction program.

Jujubede Date -- This Chinese herb has been used for centuries to calm the mind and nourish the body. Recent research has shown it has a wonderful calming effect and has analgysic properties (reduces pain/discomfort).

L-Glutamine -- This special amino acid is a precursor to Glutathione which is one of the major proteins in the brain that protects the brain from dangerous free radicals. L-Glutamine is also involved in the synthesis of numerous neurotransmitters including Gaba which has a wonderful calming effect.

L-Tyrosine -- The body uses this amino acid to produce more Dopamine and Adrenaline. When both L-Tyrosine and DL-Phenylalanine are present in people with abnormally high dopamine levels (smokers and drug users), the body raises its dopamine levels toward normal levels without the use of nicotine. Dopamine is involved in thinking, cognition, memory and excitement. Sufficient amounts are critical for normal brain function especially when people discontinue addictive drugs.

N-Acetyl-L-Cysteine -- Known as NAC, this potent antioxidant is also an excellent product designed to help clear lungs of mucus and phlegm caused by smoking. In Europe, NAC is used as an asthma medication in inhaler form. NAC improves lung functioning in normal adults but is especially effective in clearing lungs clogged by years of smoking and air born pollution. NAC is a precursor to glutathione which is a major detoxifying substance in the body.

Oleanolic Acid --This compound occurs in numerous plants. It helps to lower blood sugar, relieve pain and inflamation.

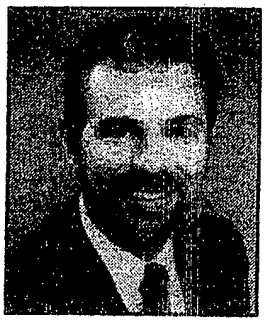
Peppermint Leaf -- Used for centuries as a treatment for colds, chest infections and breathing problems; this natural herb is very effective at helping to breakup lung congestion. The compounds in Peppermint leaf are actually volatile oils. Peppermint has been used around the world for its anti-inflammatory properties. It may help to repair damaged lung tissue while clearing breathing passages.

Pepper black (Bioperine extract) – A patented extract of black pepper to help dramatically increase the absorption of many nutrients.

Phaseolamin -- This all-natural compound extracted from plant legumes inhibits the body's conversion of carbohydrates into sugar. When carbohydrates are consumed the body releases a family of enzymes called Amylase, that converts these carbohydrates into simple sugar, which are the only way carbohydrates can be absorbed by the body. Phaseolamin reduces Amylase ability to digest carbohydrates. This results in less sugar being absorbed and fewer calories.

Super Citrimax -- A special extract of Garcinia Cambogia that has been extensively studied for its ability to reduce the cravings for carbohydrates and reduce blood lipid levels. Garcinia Cambogia reduces the appetite by inhibiting the activity of the enzyme ATP- Citrate-Lyase, which converts excess sugar into fat. The cravings for food and carbohydrates are diminished.

Vanadium -- This trace metal has been shown in some studies to be a natural mimic for insulin. It helps the body's cells to absorb sugars without causing insulin's fat creation. This may reduce insulin production, stabilize blood sugar and reduce cravings.



Ronald B. Gorayeb

The founder of Gorayeb Seminars, Inc., Ron Gorayeb, has been conducting behavior modification and human skills development programs since 1972. He has developed specialized programs for AT & T, Warner Lambert, Polygram Records, American Institute of Banking and numerous other corporations. Ron has been a practicing hypnotist for twenty years. In addition to his degrees in science, Ron has certifications in hypnosis, hypnotherapy, and neurolinguistics. Mr. Gorayeb has trained over 50,000 individuals in the practices and benefits of utilizing the subconscious mind to accomplish positive changes in both behavior and attitude.

Kenneth Coscia

Ken Coscia received his B.S. degree specializing in Managerial Psychology from Boston University and has been creating and presenting personal and professional development programs for over 30 years. As a certified hypnotherapist for over 12 years, Ken has worked with organizations throughout the U.S., Canada, Australia, Europe and the Far East. He specializes in training professional hypnotherapists in advanced hypnotic techniques. An expert in curing sleep disorders, Ken has worked with St. Frances Care Today programs and many of the leading hospitals in America.

Joseph Zawacki

Joseph Zawacki has been a corporate trainer and seminar instructor since 1969 and was Director of Training for the Ethan Allen Corporation and Vice President of Roth Young, a national executive search firm. Joseph holds a Masters Degree in Psychology with two additional years study in Industrial Psychology at the doctoral level and has been a practicing hypnotherapist for twenty years. He is the author of a book on management published in 1991 and has six years experience in professional broadcasting. Joe brings a wealth of experience to his work with Gorayeb Seminars, Inc.

James Needham

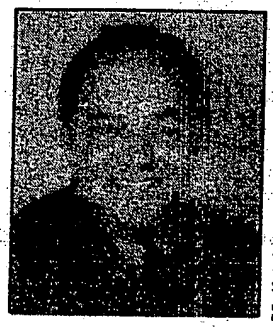
James Needham has been a practicing hypnotist for the past twenty seven years. An expert in Ericksonian Hypnosis, the Lecron-Bordeau method and the Davis Husband Method of Hypnosis, Jim has conducted in depth hypnosis training seminars for professional hypnotists. He has presented these programs throughout the United States, Australia, New Zealand, Canada, England, & Mexico. Prior to his career in hypnosis, Jim was a flight instructor for the US Air Force.

Sandra L. DeLis

Sandra DeLis obtained her Masters Degree in Clinical Social Work from Tulane University. She is a practicing psychotherapist and Clinical Hypnotherapist. Her background includes extensive inpatient psychiatric work, specializing in addictions, eating disorders and behavioral disorders at River Oaks Psychiatric Hospital in New Orleans, Louisiana and the Renfrew Residential and Treatment Center in Coconut Creek, Florida.

Thomas Mahas

Tom holds Psychology and Sociology degrees plus a Masters Degree in Education. He has been a practicing hypnotherapist since 1976. For the last 20 years, Tom has specialized in conducting programs for habit modification in Australia, the Asian Rim, Japan, Hong Kong and New Zealand. He returned from Australia to work with Gorayeb Seminars.



Norman LaClair

Norman LaClair is a licensed Master Practitioner of Neurolinguistic Programing as well as a Master of Clinical Hypnosis. He was in private Clinical practice for many years while also presenting hypnotherapy and neurolinguistic educational programs at educational and medical associations throughout the United States. Norman is a former member of the Board of Directors for the Hypnosis Hall of Fame.

Mark Pasnak

Mark Pasnak has been an international training consultant for several Fortune 500 companies since 1975. An accomplished speaker and instructor, he has traveled extensively throughout the U.S. and Europe training thousands of people in the areas of behavior modification and goal achievement. Mark is a practicing Clinical Hypnotherapist specializing in weight loss and smoking cessation. He brings to Gorayeb Seminars a broad wealth of experience helping people to improve their lives.